This response to comment document addresses cross cutting public comments that may be applicable to issues impacting all ten chemicals. The responses here represent EPA's preliminary reactions to some of the comments received, as the Agency has not reached final decisions on the approaches to the 10 risk evaluations. The Agency invites the public to provide additional comments on these Problem Formulation documents if their comments/issues have not been sufficiently addressed.

General comments

1. Many commenters asked for clarification on how the problem formulations will be different than the scope documents. Commenters added that these scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations (0741-0059, 0741-0060). One commenter added that "it is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. The commenter believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified.

   Response: EPA agrees that TSCA requires that scope documents include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. EPA believes the scope documents did that, although without the level of specificity EPA expects for future risk evaluations. As explained in each of the scope documents,

   "To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

   Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for [chemical name]."

   EPA has published the Problem Formulation documents which refine these 10 scope documents. The conceptual models and analysis plans in the problem formulation documents more clearly identify the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations the Administrator expects to consider in risk evaluations for the first ten chemicals. Additional specificity around some of these general components (e.g., particular exposure parameters, points of departure for hazards, susceptible subpopulations based on greater susceptibility) of a risk evaluation cannot be provided until data and models are reviewed and analyses conducted. These activities and further analyses occur during the Analysis Phase of risk evaluation and will be presented in the Draft Risk Evaluation.

Conditions of Use

2. EPA received a number of comments regarding the conditions of use. Commenters urged EPA to consider the chemical substance as a whole and therefore to consider all conditions of use, and that

EPA does not have discretion to ignore certain uses (0741-0059, 0735-0052), including de minimis uses (0741-0061). Other commenters added that EPA should consider reasonably foreseeable uses like accidents, misuses, and off-label uses, whole lifecycle of the chemical including legacy, and non-TSCA uses (0741-0061, 0741-0062, 0741-0056, 0741-0029). One commenter specifically questioned the exclusion of accidents, stating that the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks (0741-0059).

Specifically, regarding legacy uses, two commenters added that legacy uses should be considered (0735-0052) (0741-0057), and others noted that there are six chemicals that contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. These commenters stated that ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations (0741-0060, 0741-0062). Additionally, one commenter added that by-product or contaminant uses should also be added (0741-0057).

Response: As discussed at length in the preamble to the final risk evaluation rule, based on legislative history, statutory structure and language, and other evidence of Congressional intent, EPA has identified certain activities that may generally not be considered to be conditions of use. EPA does not generally intend to include intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in a chemical substance's risk evaluation. EPA's judgment is supported by the legislative history, and public comment suggesting that "the term 'conditions of use' is not intended to include 'intentional misuse' of chemicals." See, for example Senate Report 114–67, page 7. Similarly, EPA interprets the mandates under section 6(a)–(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), and consequently does not generally intend to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal.

EPA further explained that it may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. This includes uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks. EPA may determine that there are appropriate regulatory safeguards in place for a particular use or that a particular use is de minimis, and that these uses can be excluded from further assessment as part of the risk evaluation. Finally, EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes and which EPA does not expect to include in the risk evaluation. See, 82 Fed Reg at 33729-33730 for further details on EPA's reasoning.

EPA also indicated in the preamble to the Risk Evaluation rule, and again in the chemical scope

documents, that it intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping. EPA went on to explain that there may be several different technical and policy perspectives in which to consider evaluating the risks of impurities, including to evaluate the potential risks within the scope of the risk evaluations for the impurity itself, within the scope of the risk evaluation for the separate chemical substances that bear the impurity, and not including the impurity within any risk evaluation where EPA has a basis to foresee that the risk from the impurity would be *de minimis* or otherwise insignificant.

The problem formulation document for each of the first 10 chemicals has been refined based on comments and input on the scope documents. The problem formulation more clearly presents what conditions of use and associated exposure pathways will be evaluated in the risk evaluation and provides rationales for EPA's decisions.

Systematic Review

3. Two commenters request that the Agency conduct systematic review to identify the hazard as these methods will strengthen and increase transparency. Specifically, 0741-0052 stated that EPA should conduct hazard identification by following systematic review processes that integrate animal, human, and mechanistic evidence and that EPA should heed the NAS recommendation to conduct risk evaluations by identifying any existing systematic reviews for a chemical substance, determining if the reviews are of high quality, and for those that are, building upon the reviews by incorporating any more recent studies that may have become available since the review was conducted (0741-0052). Another commenter provided a number of ways to improve the Agency's literature search and systematic review strategies to strengthen its evaluations and increase transparency (0741-0057).

   Response: As stated in the Risk Evaluation rule, EPA believes that integrating systematic review into the TSCA risk evaluations is critical to meet the statutory requirements of TSCA. EPA agrees that there are universal components of systematic review that EPA intends to apply in conducting risk evaluations. EPA has also concluded it would be premature to codify specific systematic review methods and criteria since these may change as the Agency gains more experience conducting TSCA risk evaluations.

   Along with the problem formulation documents, EPA is publishing a supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*, which contains details about the systematic review process and strategy for assessing data quality that OPPT plans to use for these first ten chemical risk evaluations. Integrating systematic review principles into the TSCA risk evaluation process is critical to develop transparent, reproducible and scientifically credible risk evaluations.

   EPA/OPPT plans to implement a structured process of identifying, evaluating and integrating evidence for both the hazard and exposure assessments developed during the TSCA risk evaluation process. The systematic review process will use existing systematic reviews as a starting point to identify relevant references and supplement these with any more recent information. It is expected that new approaches and/or methods will be developed to address

specific assessment needs for the relatively large and diverse chemical space under TSCA. Thus, EPA/OPPT expects to document the progress of implementing systematic review in the draft risk evaluations and through revisions of this document and publication of supplemental documents.

~~OPPT is developing procedures for conducting systematic review associated with TSCA risk evaluations (at least for the first 10 chemicals) in a step-wise fashion in parallel with conducting the phases of the risk evaluation. The phased approach is necessary given the statutory timeframes imposed on EPA. Each of the steps of systematic review are being published in parallel with steps in the risk evaluation. For example, when scope documents were published, each included a description of the first step in systematic review, i.e., Data and Information Collection (section 1.3 in Scope documents), and EPA published a *Strategy for Conducting Literature Searches: Supplemental Document to the TSCA Scope Document* for each of the ten chemicals. This supplemental document described OPPT's initial methods, approaches and procedures for identifying and screening publicly available information supporting TSCA risk evaluation. With the problem formulation documents, EPA is publishing another supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*, which contains additional details about the systematic review process and strategy for assessing data quality that OPPT plans to use for the TSCA risk evaluations. These procedural documents provide an explanation to the public regarding how the Agency is conducting systematic review for the first 10 chemicals and how it plans to review future chemicals. EPA is accepting and will consider public comments on these documents when revising future procedures and conducting future systematic reviews.~~

Commented [BS1]: This language is taken from the SR doc

Commented [WJ2]: This is confusing to me because I thought the application of systematic review document encompasses all remaining steps of systematic review but this description suggests there will be more systematic review related documents that will be published with other steps in the RE process. Is that correct?

Also the description of the systematic review document in the SR itself describes what it does differently than this comment response. The SR document (the last version I commented on) states:

This document describes the systematic review process that EPA/OPPT plans to apply in the risk evaluation process for the first ten chemicals, which EPA/OPPT initiated on December 19, 2016, as well as future assessments.
. . .
To assist EPA in meeting the TSCA science standards, EPA/OPPT generally intends to apply the systematic review process described in Figure 2-1 for the first ten chemicals and future chemicals.

Commented [WJ3]: Will there be a separate document for each step? Are the steps those listed in figure 2-1 of the systematic review document? It appears that the lit search document would cover "data collection" from figure 2-1 and perhaps 'assessing data quality', mentioned below' would cover the 'data evaluation' step in figure 2-1. There are other steps in figure 2-1 (data integration and summary of findings and risk characterization). Will there be different publications related to systematic review for each of those?

Commented [WJ4]: I'm confused by this terminology. I understand systematic review to be a verb, a process. This uses the term as a noun. Should it be used in both ways or should this last sentence be reworded to say something like "when revising future procedures for systematic review purposes"?

Exposure

4. A number of commenters provided input regarding how the Agency will assess chemical exposures, specifically with regard to engineering controls. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). (0741-0059, 0741-0062, 0741-0029, 0741-0057). Another commenter added that, in evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective. The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls (0741-0060).

Response: OPPT's approach for developing exposure assessments for workers is to use best available information to construct realistic exposure scenarios based on data and information regarding real-world use of chemicals. When appropriate, in the risk evaluation, OPPT ~~develops~~ will

use exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-by-case basis for a given chemical.

5. There were a number of comments urging EPA to assess aggregate exposures within populations in the problem formulations, and stating that failing to do so would underestimate the risk of the chemicals. (0735-0052, 0741-0057, 0741-0060, 0741-0061, 0741-0029)

   Response: The statute requires that the Agency describe whether aggregate (or sentinel) exposures were considered, see 15 USC 2605(b)(4)(F)(ii); whichever exposure assessment method is ultimately used will be accompanied by an explanation in the Risk Evaluation. In conducting an aggregate exposure assessment, EPA may also include exposures from non-TSCA uses, e.g., as part of background; whether and how to account for such exposures will be evaluated on a case-by-case basis. EPA will consider whether to assess aggregate exposure when developing the exposure assessment during the Analysis Phase of the Risk Evaluation.

6. Two commenters asked how EPA will incorporate cumulative risk, as well as aggregate, in the first 10 risk evaluations. Commenters added, to properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. (0741-0060, 0741-0061)

   Response: Cumulative exposure is not required under the statute. EPA retains the discretion to conduct a cumulative assessment but has not yet determined whether to do so for any of the first 10 risk evaluations. However, EPA may ultimately determine that for a certain chemical or category a cumulative exposure assessment is appropriate for certain endpoints.

Hazard

7. One commenter asked EPA not to prejudge the absence of adverse effects for particular end-points at the scoping stage but to defer such conclusions until the systematic review phase of its risk evaluation as the law requires (0741-0060).

   One commenter expressed concern that EPA says in all the chemical scoping documents in the Section on Environmental Hazards that it expects to consider other studies, including data from alternative test methods such as computational toxicology, bioinformatics, high-throughput screening methods, read-across data, etc. Many of these alternative test methods, and particularly their application to risk assessment, are still emerging and, although promising, have serious limitations. However, if utilized prematurely or incorrectly, these tools could allow for the rapid and erroneous exoneration of harmful chemicals. These tools lack complete biological coverage, cannot presently evaluate the potential toxicity associated with chemical metabolism and absorption, and have the potential for high false negatives relative to whole animal studies (0741-0062).

   Response: EPA does not intend to prejudge any conclusions before systematic review is conducted in the risk evaluations. OPPT is aware of the status of alternative test methods with regard to the methodological validation, standardization and acceptance (e.g., established OCSPP or OEC Test Guideline vs. basic research approach). Regardless of the level of regulatory or international recognition, data from other studies and alternative test methods can inform

risk evaluation if they are determined to be consistent with the best available science and can inform the weight of the scientific evidence. Like other, more traditional testing studies, all studies conducted using non-guideline approaches or using alternative test methods will undergo systematic review to evaluate data quality and relevance. In addition, all risk evaluations will be subject to public comment and independent peer review. OPPT anticipates use of data from alternative test methods.

TSCA section 26(h) requires that, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, EPA must use scientific information, technical procedures, measures, methods, protocols, methodologies, or models consistent with the best available science. TSCA section 26(i) requires EPA to make decisions under TSCA sections 4, 5, and 6 based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).

8. One commenter stated that three chemicals (carbon tetrachloride, methylene chloride and 1-bromopropane) have data showing a high ozone depletion potential and that this should fall within the scope of the risk evaluation (0742-0060).

   Response:

   Regulation of ozone-depleting substances (ODS) falls under the jurisdiction of the Clean Air Act, administered by EPA's Office of Air and Radiation. Because ozone depletion risks are adequately assessed and effectively managed under the Clean Air Act, EPA does not expect to include ozone-depletion potential in risk evaluations for carbon tetrachloride, methylene chloride or 1-bromopropane. EPA regulations under Sections 601-607 of the Clean Air Act phase out the production and import of class I and class II ODS ([HYPERLINK "https://www.epa.gov/ods-phaseout"]) with limited exceptions. Carbon tetrachloride is subject to these regulations, addressing its ozone-depletion risks. Furthermore, under Section 612 of the CAA, EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ODS. New chemicals that are proposed as substitutes are reviewed in coordination with OCSPP's New Chemicals Program, and significant new uses of existing chemicals are also reviewed under the SNAP program. Various environmental and health risks of methylene chloride and 1-bromopropane (n-propyl bromide), including their ozone-depletion potential, have been evaluated for specific uses under the SNAP program.

Commented [GB5]: Not sure I get the import of this OAR addition. The three chemicals are HAPs, correct? The PFs say we are not evaluating any exterior air pathways for these, right? Are these provisions referenced here part of the HAPS program? If not, are these additional reasons not to evaluate this aspect of potential risk from air emissions?

Commented [BS6R5]: Should this be removed then?

Health Protective Defaults

9. A number of commenters urged EPA to use health-protective defaults if the agency lacks information specific to a chemical, and health-protective methods to quantify risk when characterizing risk (0741-0052, 0741-0057, 0741-0062). Specifically, for cancer, a commenter highlighted the NAS recommendation that EPA include a factor to account for human variability in response to carcinogens, as EPA's current approach inaccurately assumes that there is no variability in response. Similarly, EPA should increase or add factors that address cancer and non-cancer susceptibility during early life stages (0741-0057).

   One commenter urged EPA not to use MOE (margin of exposure) as an analysis method in the risk evaluation process, as MOE is not an estimate of risk—it is a single number that is a version of the

"bright line" approach like the Reference Dose (or Reference Concentration for inhalation doses) (0741-0057).

Response: EPA does not want to *a priori* preclude the use of any methods or data types, to allow its evaluations to change as science advances. EPA will utilize current policies, models, and screening methods, but is committed to being consistent with the ~~using~~ best available science and weight of the scientific evidence approaches to guide the Agency in using this information. EPA recognizes the advancing science to inform risk evaluation and will not discourage the use of new methods as long as they are consistent with the standards in section 26 of TSCA. EPA also recognizes that different approaches require different types and amounts of data and will select and employ methods that are fit for purpose within the context of a particular risk evaluation. In some cases, it may be necessary to utilize default parameters in modeling and risk calculations, and to utilize conservative assumptions, whereas in other cases assumptions may be replaced with specific or specialized data. ~~EPA will fully describe the selection of risk characterization methods, and the uncertainties associated with them~~. It should also be noted, in addition, their use will be peer reviewed, and the public will have the opportunity to comment on them during the public comment periods.

Commented [GB7]: Does the RE rule already require what we are committing to in this sentence? Best not to commit to more than we are already obligated to do (or at least to make sure that any additional commitment is carefully thought through).

EPA has utilized the MOE approach in previous risk assessments, citing its utility. However, EPA does agree with comments that there are numerous ways to characterize risk, of which MOE is just one. There will be risk scenarios where one approach may be better than another and, as commenters correctly pointed out, the science of risk characterization is still evolving, particularly for non-cancer hazards. Hence, OPPT will use risk characterization approach(es) suitable for the purpose of the risk evaluation and that the best available science and data support. EPA does not agree with the commenter that the use of MOEs is never appropriate.

Confidential business information (CBI)

10. A number of commenters added comments regarding CBI. Two requested EPA require that claims of confidential business information be fully substantiated by industry and not used to conceal critical information from the public (0741-0052, 0741-0057, 0074-0059). Another added that EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired (0741-0060).

    One commenter added that the strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available EPA must review it (0741-0059).

    Additionally, this commenter raised the question as to whether this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the

Lautenberg Act. Historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act (0741-0059).

Response: TSCA requires that CBI claims must be asserted and substantiated concurrently with the submission of information, except for information that is deemed exempt under TSCA section 14(c)(2).

The risk evaluation rule does clarify that the agency does consider CBI as "reasonably available information" and will utilize it in risk evaluations were relevant.

While it is correct that the *Application of Systematic Review in TSCA Risk Evaluations* indicates the procedure for searching the public literature does not include "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information", since these search engines/methods would not be able to locate such information, OPPT is searching internal information it may possess as part of the process of conducting the risk evaluations. EPA will comply with TSCA section 14 review and disclosure requirements for data/information that is claimed confidential and deemed relevant for the risk evaluation.

Potentially exposed and susceptible subpopulations

11. Commenters provided feedback regarding EPA's approach to identifying "potentially exposed or susceptible subpopulations." One commenter suggested that EPA address susceptible sub-populations, following recommendations from the National Academies of Sciences (NAS) to identify susceptible sub-populations based on established extrinsic and intrinsic factors that increase vulnerability (0741-0057).

    Another commenter suggested the language provided in the scopes was general "boilerplate" descriptions of such subpopulations, adding that further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor that TSCA requires (0741-0060). Similarly, a commenter asked for more clarification in the problem formulation documents of those populations with greater susceptibility (0741-0059).

    Another commenter encouraged EPA to consider for every chemical review: (1) occupational exposures that are often at much higher exposure levels than the general public, both acutely and chronically, and can be concurrent with other chemical exposures at the workplace; (2) fence-line communities who also face multiple exposures to multiple chemicals and suffer from many chronic health conditions and health inequalities; (3) sensitive time periods during life, such as pregnancy and during childhood; (4) tribal communities where cultural and lifestyle considerations may result in very different exposure profiles and where there are often disproportionate adverse health outcomes; and (5) general variability in human responses. The commenter encouraged EPA to actively seek input from fence-line and other impacted communities, occupational workers at manufacturing, processing, distributing, or recycling facilities, concerned members from the public, and tribal communities and incorporate their concerns in the Agency's evaluations where appropriate." (0741-0029)

A commenter added comments specifically regarding occupational exposure: Occupational workers exposed during the manufacture, processing, disposal, etc. of these chemicals should always be considered separately as a susceptible population. Furthermore, the consideration of exposed workers should always include the potential for pregnant women and consider both women and men of childbearing age as a vulnerable population when assessing the risk (0741-0029 and 0741-0059).

Finally, one commenter urged the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. The commenter also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment (0741-0061).

Response: While EPA wholly agrees that protecting potentially exposed or susceptible subpopulations is an important part of EPA's mandate, the process for identifying the subpopulations considered in each risk evaluation will be case specific and, consistent with the directive in section 6(b)(4)(A), tailored as relevant to the risk evaluation. Furthermore, EPA will use the best available science and prevailing guidance, such as recommendations of the NAS, in defining and assessing such subpopulations.

Every risk evaluation must consider any 'potentially exposed or susceptible subpopulations' determined to be relevant to the risk evaluation under the conditions of use. However, potentially exposed or susceptible populations and subpopulations can vary depending on the chemical and conditions of use being evaluated. EPA is required by statute to consider relevant potentially exposed or susceptible subpopulations, which could include children, pregnant women, and other subpopulations as appropriate for the assessment. For example, when appropriate, EPA will include specific life-stages ~~of childre~~exposure scenarios which may be~~are~~ more representative of various exposures ~~scenarios~~ that affect children.

Likewise, if workers are determined to be a population likely to be~~(2)~~ exposed to a chemical during its conditions of use, this population would be included as a 'potentially exposed or susceptible subpopulation' and therefore considered in the risk evaluation. In fact, in the scope documents, EPA identified both workers and consumers as susceptible subpopulations on the basis that they are more exposed than the general population to chemicals and/or products that the general population does not work with or use. EPA acknowledged in the scope documents that measurement and evaluation methods for these, and potentially other, subpopulations is still being refined.

EPA welcomes information from communities and will use it to further refine risk evaluations.

To this end, EPA has already sought input from specific populations and public health experts in implementing TSCA and will continue to do so. For example, EPA has had discussions on several occasions with the National Tribal Toxics Council to receive input on tribal lifeways and exposures. OPPT and the NTTC continue to collaborate on ways to consider tribes in conducting potentially exposed or susceptible subpopulations analyses for Draft Risk Evaluations. OPPT has also had several meetings with AFL-CIO about workers as potentially exposed or susceptible

subpopulations and ways in which worker exposure information could be identified and provided for use in the risk evaluation process. OPPT has also sought advice and input regarding children as a susceptible subpopulation from the Children's Health Protection Advisory Committee (CHPAC) through a meeting and recommendations addressing the formal request from EPA for guidance on how risk evaluation should address children. CHPAC's recommendations can be found [HYPERLINK "https://www.epa.gov/sites/production/files/2017-04/documents/2017.03.30_chpac_tsca_letter.pdf"].

IRIS Assessments

12. A few commenters urged EPA to use existing IRIS assessments (0741-0061, 0741-0062). Specifically, EPA should rely on existing IRIS assessments for hazard identification, and moving forward, EPA should complete hazard identification or add additional studies only through a systematic review process, which integrates animal, human and mechanistic evidence as recommended by the recent NAS report (0741-0057). EPA does not need to revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address (0074-0060).

    Response: As discussed in the scope documents, where applicable, OPPT has used IRIS documents as a starting point for identifying key and supporting toxicity studies and initial hazard identification. However, EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. Specifically, EPA will screen information developed after the completion of any IRIS assessment and evaluate all information OPPT's structured process described in the documents *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act* (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.*

Information Gathering

13. EPA received a number of comments on information gathering.

    "EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA [sections] 4 and 8 to obtain additional information. The scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is reasonably available information. Additionally, any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps." (0741-0059).

    Response: The commenter is correct, as the scope documents should refer to "reasonably available information", not "readily available". In the risk evaluation rule, EPA defined reasonably available information to mean information that EPA possesses, or can reasonably

Commented [GB8]: I don't think the responses here are very strong. It would help if we could be more specific about why we, at least as of this point, think we have the reasonably available information needed for these REs. For example, can we get more mileage out of the fact that we purposefully picked these first 10 chemicals because they are data-rich?

Commented [GB9]: If we really said this, we should acknowledge in the comment response that it was a mistake and the standard is reasonably available.

Commented [GB10]: We don't really respond to these comments. The commenter clearly seems to be saying we are falling short of our obligations in these 10 evaluations, and our response is a general treatise on what we think reasonably available means.

obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. EPA agrees that it makes sense to view information that can be obtained through testing as "reasonably available" in some instances – especially information that can be obtained through short-term testing, where it can be obtained within the relevant statutory deadlines and the information would be of sufficient value to merit the testing. EPA will consider use of its information gathering authorities under section 8 on a similar basis – i.e., considering the statutory deadlines and the value the additional information would likely have in reducing uncertainty in its fit-for-purpose evaluations. As discussed in the prioritization rulemaking, EPA will seek to generally ensure that sufficient information to complete a risk evaluation exists and is available to the Agency prior to initiating the evaluation. For these first ten risk evaluations, EPA believes that these are generally data-rich chemicals, and the use of our data gathering authority is not warranted. However, EPA also recognizes that there may be circumstances where additional information may need to be developed within the time frames of the risk evaluation process. This may include information developed through the use of novel and advancing chemical assessment procedures, measures, methods, protocols, methodologies, or models (e.g., high-throughput chemical assessment techniques). EPA will tailor its information gathering efforts as appropriate.

Commented [GB11]: OPPT and OGC: consider this addition. I think we need to set up the argument that we don't have to get all the information we have the authority and time to get – since we haven't used regulatory authority to get any so far and don't seem inclined to. Another idea I think we want to work in at some point is that, when we talk about the ability to get the info within the statutory deadlines, I think that needs to be informed by the range of other work OPPT is doing. Ie, the deadlines for the 10 REs don't exist in a vacuum. But given the on-going RE litigation, we probably don't want to start expanding on this now.

"Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties." (0741-0060)

Response: To date, EPA has gathered extensive use and exposure data for these then chemicals and believe we have adequate use and exposure info. We will seek to obtain more if we find we need it. ~~Given the statutory deadlines imposed by TSCA, EPA generally believes that problem formulation may be too late to identify critical data insufficiencies. Therefore, EPA plans to collect information and conduct an assessment of data availability/landscape prior to designating a chemical in the Prioritization process.~~

Commented [GB12]: I don't really follow this response. If we haven't identified critical data insufficiencies, we can say that. Presumably, though, if we did identify one, we would have to figure out some way to fill it. So it seems awkward to say it's too late. Can we say instead that, to date, we believe we have adequate use and exposure info and will seek to obtain more if we find we need it, or something like that? And also point out that we have gathered extensive use and exposure data for these chemicals as the first step?

"Absence of data does not equal no risk, and efforts to obtain data should occur immediately" (0741-0029).

Response: OPPT does not believe that absence of data equals no risk. ~~However, TSCA does not require specific types or quantities of data; rather, it requires that scientific information, technical procedures, measures, methods, protocols, methodologies, or models be employed in a manner consistent with the best available science. When~~ However, when OPPT does find existing data are not adequate, , OPPT will use all available authorities to fill data gaps necessary to conduct fit-for-purpose assessments, or utilize conservative assumptions to determine risk. As discussed previously, due to the deadlines mandated in TSCA, information must be reasonably available within the constraints of the timeframes imposed.

Commented [GB13]: This reference to sec 26 standards is confusing, because the section 26 standards include the requirement in sec 26(k) to base decisions on reasonably available information. So, it seems circular to say we will collect reasonable available information when we don't have reasonably available information.

Commented [GB14]: Can we say that, in the absence of data, far from assuming no risk as the commenter suggests, we often employ conservative assumptions?

"When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information" (0741-0059).

Response: Prior assessments would undergo the same systematic review procedures as other information used in a risk evaluation.

"EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals, and this does not constitute all "reasonably available" information. By contrast, If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information." (0741-0059)

Response: EPA has not indicated it would rely solely on voluntary requests for information.

Commented [GB15]: Haven't we in effect done so, by not employing our info collection authorities to date, and indicating above that we think it's late in the game to start doing so?

"EPA should use section 4, 8(a), 8(c), 11 and 26(a) to fill data gaps, as the information obtained would constitute 'reasonably available information." (0071-0061)

Response: EPA will use available authorities to fill data gaps as appropriate. However, EPA must adhere to the timeframes imposed by TSCA. In the risk evaluation rule, EPA defined reasonably available information to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. And, consistent with the risk evaluation rule preamble, EPA will consider the value of the information that would be obtained through its information collection authorities in judging whether the information is reasonably available.

Alternative Assessment

14. One commenter strongly urged EPA to conduct comprehensive alternative assessments with a priority on hazard assessment for of each of the ten chemicals under consideration. Four of the ten chemicals currently selected by EPA as priority chemicals for risk evaluation have been previously listed by EPA as "acceptable substitutes" under the Significant New Alternatives Policy (SNAP) program that reviews substitutes for ozone-depleting substances within a comparative risk framework. The need now to reevaluate these chemicals will require millions of additional taxpayer dollars for the evaluation itself, as well as potentially millions of dollars in private resources as companies move a second time to replace what EPA deems a hazardous chemical with an acceptable substitute. By using a comprehensive alternatives assessment framework that prioritizes hazard, EPA will be able to reach conclusions about each of the ten chemicals that are far less likely to result in the need for reassessment in a few years (0741-0058).

    Response: In the prioritization rule, EPA stated that an alternative assessment of substitute chemicals is more appropriate during the risk management phase.

Ongoing Section 6(a) rule makings

15. Two commenters included comments regarding the on-going section 6(a) rulemakings that may impact trichloroethylene, methylene chloride, and N-Methylpyrrolidone. One commenter specifically questions EPA's decision not to examine uses addressed by its planned 6(a) rules governing certain uses of TCE, DCM, and NMP, and furthers states that this is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses. "By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is known to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that

these uses present unreasonable risks. It would be absurd for EPA to exclude these uses unless EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals" (0741-0059).

Another commenter adds that EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals (0741-0060).

Response: Although EPA indicated in the TCE, NMP and MeCl scope documents that EPA did not expect to evaluate the uses assessed in the 2014 or 2015 risk assessment in the TCE, NMP or MeCl risk evaluation, respectively, EPA has decided to evaluate these conditions of use for TCE and NMP in the risk evaluation. EPA is including these conditions of use so that they are part of EPA's determination of whether TCE~~,~~ and NMP ~~or MeCl~~ presents an unreasonable risk "under the conditions of use," TSCA 6(b)(4)(A). EPA has concluded that the Agency's assessment of the potential risks from these widely used chemicals will be more robust if the potential risks from these conditions of use are evaluated by applying standards and guidance under amended TSCA. In particular, this includes ensuring the evaluations are consistent with the scientific standards in Section 26 of TSCA, the *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act* (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.* EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. It is important to note that conducting these evaluations does not preclude EPA from finalizing the proposed TCE and ~~,~~ NMP ~~or MeCl~~ regulation. On May 10th, 2018 EPA announced it intends to finalize the methylene chloride rulemaking proposed in January 2017. Therefore, EPA will not re-evaluate the paint stripping uses of methylene chloride and will be relying on the previous assessment.

Other

16. One commenters shared information on the "Beyond Science and Decisions" project, a risk methods compendium as a resource for regulators and scientists on key considerations for applying selected dose-response techniques for various problem formulations, with suggested techniques and resources (0741-0057).

    Response: Thank you for this comment and for the suggested resources.

This response to comment document addresses cross cutting public comments that may be applicable to issues impacting all ten chemicals.

General comments

1. Many commenters asked for clarification on how the problem formulations will be different than the scope documents. Commenters added that these scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations (0741-0059, 0741-0060). One commenter added that "it is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. The commenter believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified.

   Response: EPA agrees that TSCA requires that scope documents are to include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. As explained in each of the scope documents,

   "To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

   Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for [chemical name]. This problem formulation is expected to be released within approximately 6 months of publication of the scope."

   EPA has published the Problem Formulation documents which refine the scope documents. The conceptual models and analysis plans in the problem formulation documents more clearly identify the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations the Administrator expects to consider in risk evaluations for the first ten chemicals. Additional specificity around some of these general components (e.g., particular exposure parameters, points of departure for hazards, susceptible subpopulations based on greater susceptibility) of a risk evaluation cannot be provided until data and models are reviewed and analyses conducted. These activities and further analyses occur during the Analysis Phase of risk evaluation and will be presented in the Draft Risk Evaluation.

Conditions of Use

2. EPA received a number of comments regarding the conditions of use. Commenters urged EPA to consider the chemical substance as a whole and therefore consider all conditions of use, and that EPA does not have discretion to ignore certain uses (0741-0059, 0735-0052), including de minimis uses (0741-0061). Other commenters added that EPA should consider reasonably foreseeable uses like accidents, misuses, and off-label uses, whole lifecycle of the chemical including legacy, and non-

TSCA uses (0741-0061, 0741-0062, 0741-0056, 0741-0029). One commenter specifically questioned the exclusion of accidents, stating that the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks (0741-0059).

Specifically, regarding legacy uses, two commenters added that legacy uses should be considered (0735-0052) (0741-0057), and others noted that there are six chemicals that contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. These commenters stated that ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations (0741-0060, 0741-0062). Additionally, one commenter added that by-product or contaminant uses should also be added (0741-0057).

Response: As discussed at length in the preamble to the final risk evaluation rule, based on legislative history, statutory structure and language, and other evidence of Congressional intent, EPA has identified certain activities that may generally not be considered to be conditions of use. EPA does not generally intend to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in a chemical substance's risk evaluation. EPA's judgment is supported by the legislative history, and public comment suggesting that "the term 'conditions of use' is not intended to include 'intentional misuse' of chemicals." See, for example Senate Report 114–67, page 7. Similarly, EPA interprets the mandates under section 6(a)–(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), and consequently does not generally intend to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal.

EPA further explained that it may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. This includes uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks. Finally, EPA may determine that there are appropriate regulatory safeguards in place for a particular use or that a particular use is de minimis, and that these uses can be excluded from further assessment as part of the risk evaluation. See, 82 Fed Reg at 33729-33730 for further details on EPA's reasoning.

Commented [BC1]: Revise this language to be consistent with the words being used in the PF's.

EPA also indicated it intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping. EPA went on to explain that there may be several different technical and policy perspectives in which to consider evaluating the risks of impurities, including to evaluate the potential risks within the scope of the risk evaluations for the impurity itself, within the scope of the risk evaluation for the separate chemical substances that bear the impurity, and not including the impurity within any risk

Commented [BC2]: Where?

evaluation where EPA has a basis to foresee that the risk from the impurity would be *de minimus* or otherwise insignificant.

The problem formulation document for each of the first 10 chemicals has been refined based on comments and input on the scope documents. The problem formulation more clearly presents what conditions of use and associated exposure pathways will be evaluated in the risk evaluation and provides rationales for EPA's decisions.

Systematic Review

3. Two commenters request that the Agency conduct systematic review to identify the hazard as these methods will strengthen and increase transparency. Specifically, 0741-0052 stated that EPA should conduct hazard identification by following systematic review processes that integrate animal, human, and mechanistic evidence and that EPA should heed the NAS recommendation to conduct risk evaluations by identifying any existing systematic reviews for a chemical substance, determining if the reviews are of high quality, and for those that are, building upon the reviews by incorporating any more recent studies that may have become available since the review was conducted (0741-0052). While another commenter provided a number of ways to improve the Agency's literature search and systematic review strategies to strengthen its evaluations and increase transparency (0741-0057).

   Response: As stated in the Risk Evaluation rule, EPA believes that integrating systematic review into the TSCA risk evaluations is critical to meet the statutory requirements of TSCA. EPA agrees that there are universal components of systematic review that EPA intends to apply in conducting risk evaluations. ~~; but this is one area where~~ EPA has also concluded it would be premature to codify specific systematic review methods and criteria ~~that~~ since these may change as the Agency gains more experience conducting TSCA risk evaluations.

   OPPT is developing procedures for conducting systematic review associated with TSCA risk evaluations (at least for the first 10 chemicals) in a step-wise fashion in parallel with conducting the phases of the risk evaluation. The phased approach is necessary given the statutory timeframes imposed on EPA. Each of the steps of systematic review are being published in parallel with steps in the risk evaluation. For example, when scope documents were published, each included a description of the first step in systematic review, i.e., Data and Information Collection (section 1.3 in Scope documents), and EPA published a *Strategy for Conducting Literature Searches: Supplemental Document to the TSCA Scope Document* for each of the ten chemicals. This supplemental document described OPPT's initial methods, approaches and procedures for identifying and screening publicly available information supporting TSCA risk evaluation. With the problem formulation documents, EPA is publishing another supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*, which contains additional details about the systematic review process and strategy for assessing data quality that OPPT plans to use for the TSCA risk evaluations. These procedural documents provide an explanation to the public regarding how the Agency is conducting systematic review for the first 10 chemicals. EPA is accepting and will consider public comments on these documents when revising future procedures and conducting future systematic reviews.

Exposure

4. A number of commenters provided input regarding how the Agency will assess chemical exposures, specifically with regard to engineering controls. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). (0741-0059, 0741-0062, 0741-0029, 0741-0057). Another commenter added that, in evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective. The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls (0741-0060).

Response: OPPT's approach for developing exposure assessments for workers is to use best available information to construct realistic exposure scenarios based on data and information regarding real-world use of chemicals. Depending on the appropriateness of the analysis, OPPT develops exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks. Examples of OPPT's approach can be reviewed in previous published risk assessments for [HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-risk-assessment-0"], [HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-risk-assessment-n-0"] and [HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-risk-assessment-methylene"]. For TCE vapor degreasing, for example, the worker exposure assessment shows that worker exposure scenarios were developed with and without engineering controls (i.e., local exhaust ventilation, LEV) and personal protective equipment (gloves, respirator). OPPT also collects and uses empirical data, for example, workplace monitoring data collected by OSHA and NIOSH, to develop and/or supplement exposure modeling for workers. Again, these approaches are demonstrated in the peer reviewed risk assessments for TCE, NMP and Methylene Chloride previously developed by OPPT.

Commented [BF3]: Did all of the comments pertain to worker exposure? And is there a difference in the development of worker exposure assessments and consumer exposure assessments?

Commented [USEPA4]: Sentences 1-3 in the summary paragraph refers to 'engineering controls' or 'PPE'; ...since engineering controls and PPE cannot be required of consumers, only workers, I would say yes.
The last two sentences refer to 'workplace', 'engineering controls', 'PPE' and 'occupational exposures', 'workers', and 'industrial hygiene'. All of these words apply to workers only.

Commented [BN5]: Not sure we need these as these assessments were pre lautenbergg

5. There were a number of comments urging EPA to assess aggregate exposures within populations in the problem formulations, and stating that failing to do so would underestimate the risk of the chemicals. (0735-0052, 0741-0057, 0741-0060, 0741-0061, 0741-0029)

Response: EPA is not required to assess aggregate exposure in a risk evaluation; the statutory requirement is that the Agency describe whether aggregate (or sentinel) exposures were considered. The use of either of these exposure assessment methods will be accompanied by an explanation. See 15 USC 2605(b)(4)(F)(ii). EPA may, in conducting an aggregate exposure assessment, include exposures from non-TSCA uses, e.g., as part of background. Whether and how to account for such exposures will be evaluated on a case-by-case basis. At the point of scoping and problem formulation, data and information regarding specific exposure scenarios

are not well defined enough for EPA to consider whether aggregate exposure assessment is warranted. EPA will consider whether to assess aggregate exposure when developing the exposure assessment during the Analysis Phase of the Risk Evaluation.

6. Two commenters asked how EPA will incorporate cumulative risk, as well as aggregate, in the first 10 risk evaluations. Commenters added, to properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. (0741-0060, 0741-0061)

   Response: While cumulative exposure is often important for considering risk to populations, it is not required under the statute. EPA retains the discretion to conduct a cumulative assessment but has not yet determined whether to do so for any of the first 10 risk evaluations. However, EPA may ultimately determine that for a certain chemical or category a cumulative exposure assessment is appropriate.

Hazard

7. One commenters asked EPA not to prejudge the absence of adverse effects for particular end-points at the scoping stage but to defer such conclusions until the systematic review phase of its risk evaluation as the law requires (0741-0060).

   One commenter expressed concern that EPA says in all the chemical scoping documents in the Section on Environmental Hazards that it expects to consider other studies, including data from alternative test methods such as computational toxicology, bioinformatics, high-throughput screening methods, read-across data, etc. Many of these alternative test methods, and particularly their application to risk assessment, are still emerging and, although promising, have serious limitations. However, if utilized prematurely or incorrectly, these tools could allow for the rapid and erroneous exoneration of harmful chemicals. These tools lack complete biological coverage, cannot presently evaluate the potential toxicity associated with chemical metabolism and absorption, and have the potential for high false negatives relative to whole animal studies (0741-0062).

   Response: OPPT is aware of the status of alternative test methods with regard to the methodological validation, standardization and acceptance (e.g., established OCSPP or OEC Test Guideline vs. basic research approach). Regardless of the level of regulatory or international recognition, data from other studies and alternative test methods can inform risk evaluation if they are determined to be best available science and can inform the weight of the scientific evidence. Like other, more traditional testing studies, all studies conducted using non-guideline approaches or using alternative test methods will undergo systematic review to evaluate data quality and relevance. In addition, all risk evaluations will be subject to public comment and independent peer review. OPPT anticipates use of data from alternative test methods.

   It is also important to state that TSCA holds the Agency to a high standard when utilizing information. TSCA section 26(h) requires that, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, EPA must use scientific information, technical procedures, measures, methods, protocols, methodologies, or models consistent with the best available science. TSCA section 26(i) requires EPA to make decisions under TSCA sections 4, 5,

and 6 based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). TSCA does not explicitly define either "best available science" or "weight of the scientific evidence." Section 26(h) lists factors for the Agency to consider, as applicable, in employing best available science. These are: (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information; (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture; (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

Commented [BN6]: This information is not needed.

8. One commenter noted that three chemicals have data showing the high ozone depleting potential and that this should fall within the scope of the risk evaluation (0742-0060).

Response: EPA also identified exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes—namely, the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA)—and which EPA does not plan to include in the risk evaluation.

Commented [BN7]: Not needed for the response.

As a general matter, EPA believes that where other Federal environmental laws adequately assess and effectively manage the risks for a particular chemical, those exposure pathways do not pose risk concerns for chemicals undergoing evaluation under TSCA. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes.[1] EPA does not expect to include these identified pathways in the applicable risk evaluation.

Evaluation and regulation of chemicals related to effects on ozone fall under the purview of the Clean Air Act administered by EPA's Office of Air and Radiation.

Commented [BC8]: Should add in a couple of sentences of rationale to explain why we are not evaluating ozone effects for these three.

EPA regulations under Sections 601-607 of the Clean Air Act phase out the production and import of ozone-depleting substances, consistent with the schedules develop under the Montreal Protocol.{[HYPERLINK "https://www.epa.gov/ods-phaseout/what-phaseout-ozone-depleting-substances"]}. Carbon tetrachloride is subject to these regulations. Furthermore, under Section 612 of the CAA, EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ozone-depleting substances. Methylene chloride and 1-bromopropane (n-propylbromide) have been evaluated under the SNAP program.

Commented [BN9]: Not needed for the response

Commented [USEPA10]: OAR is reviewing this now

[1] EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern and consequently merit an unreasonable risk determination (also risk rule page 33729).

~~Furthermore, under Section 612 of the CAA, EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ozone-depleting substances.~~

Commented [BF11]: Seems like you may want to incorporate general regulatory nexus language from the PFs here. OGC added relevant language to the Introduction and Section 2.5, though it may still be subject to Nancy's review.

Commented [USEPA12]: Susanne – I have not heard back from OAR on this part...I pasted the language Bethany suggests...just in from Nancy/Erik..above; it all needs to be sewn togehter a bit

Health Protective Defaults

9. A number of commenters urged EPA to use health-protective defaults if the agency lacks information specific to a chemical, and health-protective methods to quantify risk when characterizing risk (0741-0052, 0741-0057, 0741-0062). Specifically, for cancer, a commenter highlighted the NAS recommendation that EPA include a factor to account for human variability in response to carcinogens, as EPA's current approach inaccurately assumes that there is no variability in response. Similarly, EPA should increase or add factors that address cancer and non-cancer susceptibility during early life stages (0741-0057).

   One commenter urged EPA not to use MOE (margin of exposure) as an analysis method in the risk evaluation process, as MOE is not an estimate of risk—it is a single number that is a version of the "bright line" approach like the Reference Dose (or Reference Concentration for inhalation doses) (0741-0057).

   Response: EPA does not want to *a priori* preclude the use of any methods or data types, to allow its evaluations to change as science advances. EPA will utilize current policies, models, and screening methods, but is committed to using best available science and weight of the scientific evidence approaches to guide the Agency in using this information. EPA recognizes the advancing science to inform risk evaluation and will not discourage the use of new methods as long as they are consistent with the statute's science standards. EPA also recognizes that different approaches require different types and amounts of data and will select and employ methods that are fit for purpose within the context of a particular risk evaluation. In some cases, it may be necessary to utilize defaults parameters in modeling and risk calculations, and to utilize conservative assumptions, whereas in other cases assumptions may be replaced with specific or specialized data. EPA will fully describe the selection of risk characterization methods, and the uncertainties associated with them. It should also be noted, in addition, their use will be peer reviewed, and the public will have the opportunity to comment on them during the public comment periods.

   Commented [BC13]: In the REs?

   EPA has utilized the MOE approach in previous risk assessments, citing its utility. However, EPA does agree with comments that there are numerous ways to characterize risk, of which MOE is just one. There will be risk scenarios where one approach may be better than another and, as commenters correctly pointed out, the science of risk characterization is still evolving, particularly for non-cancer hazards. Hence, OPPT will use risk characterization approach(es) suitable for the purpose of the risk evaluation and that the best available science and data support.

Confidential business information (CBI)

10. A number of commenters added comments regarding CBI. Two requested EPA require that claims of confidential business information be fully substantiated by industry and not used to conceal critical information from the public (0741-0052, 0741-0057, 0074-0059). Another added that EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired (0741-0060).

One commenter added that the strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available EPA must review it (0741-0059).

Additionally, this commenter raised the question as to whether this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. First, historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act (0741-0059).

Response: The risk evaluation rule does clarify that the agency does consider CBI as "reasonably available information" and will utilize it in risk evaluations were relevant.

While it is correct that the *Application of Systematic Review in TSCA Risk Evaluations* indicates the procedure for searching the public literature does not include "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information", since these search engines/methods would not be able to locate such information, OPPT is searching internal information it may possess as part of the process of conducting the risk evaluations. For data/information deemed relevant for the risk evaluation OPPT will conduct review of CBI claims consistent with TSCA requirements to declassify as much as possible. OPPT may also incorporate information/knowledge claimed as CBI to the extent it can be used without revealing CBI. ~~Furthermore, should information critical to the risk evaluation be deemed CBI, the application of such information by EPA may still be peer reviewed, as peer reviewers can be cleared to review CBI.~~

Potentially exposed and susceptible subpopulations

11. Commenters provided feedback regarding EPA's approach to identifying "potentially exposed and susceptible subpopulations. One commenter suggested that EPA address susceptible sub-populations, following recommendations from the National Academies of Sciences (NAS) to identify susceptible sub-populations based on established extrinsic and intrinsic factors that increase vulnerability (0741-0057).

Another commenter suggested the language provided in the scopes was general "boilerplate" descriptions of such subpopulations. Adding that further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor

Commented [DS14]: Note EPA also has statutory authority to disclose CBI "if the Administrator determines that disclosure is relevant in a proceeding under this chapter, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding". TSCA §14(d)(7); see also 40 CFR 2.306(i). It is, however, a lengthy discussion before deciding whether to even mention this here.

Commented [DS15]: If the peer reviewers are Federal employees or contractors, yes. Otherwise, no.

Commented [USEPA16]: Yes, they are SGEs

Commented [TH17]: Q for Sr.Mgmt: Not sure we want to go this far??

that TSCA requires (0741-0060). Similarly, a commenter asked for more clarification in the problem formulation documents of those populations with greater susceptibility (0741-0059).

Another commenter encouraged EPA to consider for every chemical review: (1) occupational exposures that are often at much higher exposure levels than the general public, both acutely and chronically, and can be concurrent with other chemical exposures at the workplace; (2) fence-line communities who also face multiple exposures to multiple chemicals and suffer from many chronic health conditions and health inequalities; (3) sensitive time periods during life, such as pregnancy and during childhood; (4) tribal communities where cultural and lifestyle considerations may result in very different exposure profiles and where there are often disproportionate adverse health outcomes; and (5) general variability in human responses. The commenter encouraged EPA to actively seek input from fence-line and other impacted communities, occupational workers at manufacturing, processing, distributing, or recycling facilities, concerned members from the public, and tribal communities and incorporate their concerns in the Agency's evaluations where appropriate." (0741-0029)

A commenter added comments specifically regarding occupational exposure: Occupational workers exposed during the manufacture, processing, disposal, etc. of these chemicals should always be considered separately as a susceptible population. Furthermore, the consideration of exposed workers should always include the potential for pregnant women and consider both women and men of childbearing age as a vulnerable population when assessing the risk (0741-0029 and 0741-0059).

Finally, one commenter urged the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. The commenter also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment (0741-0061).

Response: While EPA wholly agrees that protecting the most vulnerable populations is an important part of EPA's mandate, the process for identifying the subpopulations considered in each risk evaluation will be case specific and, consistent with the directive in section 6(b)(4)(A), tailored to the specific exposure from the chemical. Furthermore, EPA will use the best available science and prevailing guidance, such as recommendations of the NAS, in defining and assessing such subpopulations.

Every risk evaluation must consider any 'potentially exposed or susceptible subpopulations' determined to be relevant to the risk evaluation under the conditions of use. However, potentially exposed or susceptible populations and subpopulations can vary depending on the chemical and conditions of use being evaluated. EPA is required by statute to consider potentially exposed and susceptible subpopulations, which could include children and pregnant women. ~~However, it is not appropriate to 'always' include children and pregnant women in a risk evaluation, as it is possible that there are chemicals and/or conditions of use for which there is no children's and/or pregnant women's exposure~~. EPA~~, as appropriate,~~ will consider ~~whether to include not only children as a~~ subpopulations as appropriate for the assessment. ~~, but also~~When appropriate, EPA will also include specific life-stages of children which are more representative of various exposure scenarios that affect children.

Likewise, if workers are determined to be a population exposed to a chemical during its conditions of use, this population would be included as a 'potentially exposed or susceptible subpopulation' and therefore considered in the risk evaluation. In fact, in the scope documents, EPA identified both workers and consumers as susceptible subpopulations on the basis that they are more exposed than the general population to chemicals and/or products that the general population does not work with or use. EPA acknowledged in the scope documents that measurement and evaluation methods for these, and potentially other, subpopulations is still being refined. The data/information and systematic review thereof necessary for making definitive decisions regarding susceptible subpopulations does not occur until the Analysis Phase of the Risk Evaluation and hence, will be presented in the Draft Risk Evaluation.

EPA welcomes information from communities that are impacted by pollution and will use it to further refine risk evaluations. As implementation of this provision progresses EPA will update appropriate guidance to identify evaluated potentially exposed and susceptible subpopulations, which may include better ways to quantify risks to subpopulations.

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To this end, EPA has already sought input from specific populations and public health experts in implementing TSCA and will continue to do so. For example, EPA has ~~dialoged~~ had discussions on several occasions with the National Tribal Toxics Council to receive input on tribal lifeways and exposures. OPPT and the NTTC continue to collaborate on ways to consider tribes in conducting PESS analyses for Draft Risk Evaluations. ~~Furthermore, OPPT is committed to formal 'consultation' with tribes on the Draft Risk Evaluations.~~ OPPT has also had several meetings with AFL-CIO about workers as potentially exposed and susceptible subpopulations and ways in which worker exposure information could be identified and provided for use in the risk evaluation process. OPPT has also sought advice and input regarding children as a susceptible subpopulation from the Children's Health Protection Advisory Committee (CHPAC) through a meeting and recommendations addressing the formal request from EPA for guidance on how risk evaluation should address children. CHPAC's recommendations can be found [HYPERLINK "https://www.epa.gov/sites/production/files/2017-04/documents/2017.03.30_chpac_tsca_letter.pdf"].

Commented [BN19]: Spell out

Commented [BC20]: Did we commit to formal consultation? That can take several months to complete "formal" consultation.

IRIS Assessments

12. A few commenters urged EPA to use existing IRIS assessments (0741-0061, 0741-0062). Specially, EPA should rely on existing IRIS assessments for hazard identification, and moving forward, EPA should complete hazard identification or add additional studies only through a systematic review process, which integrates animal, human and mechanistic evidence as recommended by the recent NAS report (0741-0057). EPA does not need to revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address (0074-0060).

    Response: As discussed in the scope documents, where applicable, OPPT has used IRIS documents as a starting point for identifying toxicity studies and initial hazard identification. However, EPA has concluded that the Agency's assessment be will be more robust if the potential risks from the conditions of use are evaluated by applying the standards and guidance under amended TSCA. In particular, this includes ensuring the evaluation is consistent with the

Commented [BC21]: Check to make sure we are consistent in this RTC with the words/message we use throughout all the PFs

scientific standards in Section 26 of TSCA, the *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act* (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.* EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration.

Information Gathering

13. EPA received a number of comments on information gathering.

"EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA [sections] 4 and 8 to obtain additional information. The scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is reasonably available information. Additionally, any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps." (0741-0059).

Response: In the risk evaluation rule, EPA defined reasonably available information to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. EPA agrees that it makes sense to view information that can be obtained through testing as "reasonably available" in some instances – especially information that can be obtained through short-term testing, where it can be obtained within the relevant statutory deadlines and the information would be of sufficient value to merit the testing. As discussed in the prioritization rulemaking, EPA will seek to generally ensure that sufficient information to complete a risk evaluation exists and is available to the Agency prior to initiating the evaluation. However, EPA also recognizes that there may be circumstances where additional information may need to be developed within the time frames of the risk evaluation process. This may include information developed through the use of novel and advancing chemical assessment procedures, measures, methods, protocols, methodologies, or models (e.g., high-throughput chemical assessment techniques). EPA will, as appropriate, also require longer-term testing, and at times will need to do so to address data gaps. However, EPA does not think information that could be generated through such testing should be viewed as "reasonably available". EPA will tailor its information gathering efforts as appropriate.

"Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties." (0741-0060)

Response: Given the statutory deadlines imposed by TSCA, EPA believes that problem formulation is too late to identify critical data insufficiencies. Therefore, EPA plans to collect

information and conduct an assessment of data availability/landscape prior to designating a chemical in the Prioritization process.

"Absence of data does not equal no risk, and efforts to obtain data should occur immediately" (0741-0029).

Response: OPPT does not believe that absence of data equals no risk. However, TSCA does not require specific types or quantities of data; rather, it requires that scientific information, technical procedures, measures, methods, protocols, methodologies, or models be employed in a manner consistent with the best available science. When OPPT does find existing data are adequate to meet the section 26 standards, OPPT will use all available authorities to fill data gaps necessary to conduct fit-for-purpose assessments. As discussed previously, due to the deadlines mandated in TSCA, information must be reasonably available within the constraints of the timeframes imposed.

"When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information" (0741-0059).

Response: Prior assessments would undergo the same systematic review procedures as other information used in a risk evaluation.

"EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals, and this does not constitute all "reasonably available" information. By contrast, If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information." (0741-0059)

Response: EPA has not indicated it would rely solely on voluntary requests for information.

"EPA should use section 4, 8(a), 8(c), 11 and 26(a) to fill data gaps, as the information obtained would constitute 'reasonably available information." (0071-0061)

Response: EPA will use all available authorities to fill data gaps as appropriate. However, EPA must adhere to the timeframes imposed by TSCA. In the risk evaluation rule, EPA defined reasonably available information to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation.

Commented [BN22]: Need a caveat here.

Alternative Assessment

14. One commenter strongly urged EPA to conduct comprehensive alternative assessments with a priority on hazard assessment for of each of the ten chemicals under consideration. Four of the ten chemicals currently selected by EPA as priority chemicals for risk evaluation have been previously listed by EPA as "acceptable substitutes" under the Significant New Alternatives Policy (SNAP) program that reviews substitutes for ozone-depleting substances within a comparative risk framework. The need now to reevaluate these chemicals will require millions of additional taxpayer dollars for the evaluation itself, as well as potentially millions of dollars in private resources as

companies move a second time to replace what EPA deems a hazardous chemical with an acceptable substitute. By using a comprehensive alternatives assessment framework that prioritizes hazard, EPA will be able to reach conclusions about each of the ten chemicals that are far less likely to result in the need for reassessment in a few years (0741-0058).

Response: In the prioritization rule, EPA states that an alternative assessment of substitute chemicals is more appropriate for risk management.

Ongoing Section 6(a) rule makings

15. Two commenters included comments regarding the on-going section 6(a) rulemakings that may impact trichloroethylene, methylene chloride, and N-Methylpyrrolidone. One commenter specifically questions EPA's decision not to examine uses addressed by its planned 6(a) rules governing certain uses of TCE, DCM, and NMP, and furthers states that this is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses. "By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is known to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses unless EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals" (0741-0059).

    Another commenters adds that EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals (0741-0060).

    Response: Although EPA indicated in the TCE, NMP and MeCl scope documents that EPA did not expect to evaluate the uses assessed in the 2014 or 2015 risk assessment in the TCE, NMP or MeCl risk evaluation, respectively, EPA has decided to evaluate these conditions of use in the risk evaluation. EPA is including these conditions of use so that they are part of EPA's determination of whether TCE, NMP or MeCl presents an unreasonable risk "under the conditions of use," TSCA 6(b)(4)(A). EPA has concluded that the Agency's assessment of the potential risks from these widely used chemicals will be more robust if the potential risks from these conditions of use are evaluated by applying standards and guidance under amended TSCA. In particular, this includes ensuring the evaluations are consistent with the scientific standards in Section 26 of TSCA, the *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act* (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.* EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. It is important to note that conducting these evaluations does not preclude EPA from finalizing the proposed TCE, NMP or MeCl regulation.

Other

16. One commenters shared information on the "Beyond Science and Decisions" project, a risk methods compendium as a resource for regulators and scientists on key considerations for applying selected dose-response techniques for various problem formulations, with suggested techniques and resources (0741-0057).

    Response: Thank you for this comment and for the suggested resources.

OVERARCHING COMMENTS:

1. The exclusion of numerous conditions of use, exposure pathways, routes, and scenarios from Amended TSCA risk assessments is counter to the intention of the Lautenberg Act and will prevent comprehensive assessment of risk to children.

The intention of the Lautenberg Act was to conduct risk determination for all conditions of use. Consistent with Amended TSCA, the Problem Formulation drafts' introduction sections state that TSCA is "the Nation's primary chemicals management law." If Amended TSCA is functioning as the primary chemical's management law, then all conditions of use need to be included in the TSCA risk evaluations. All conditions of use, pathways, routes, and scenarios must be included so that risk evaluations under Amended TSCA are performed using the best available science and considering potentially exposed or susceptible subpopulations.

- **The regulatory nexus has not been adequately justified, assessed, or documented. Other laws and programs may not adequately account for potentially exposed or susceptible subpopulations (PESS) and children's health protection.** The uses, exposure pathways, and routes that remain in the Problem Formulation drafts are based largely on coverage by other laws/programs and consideration of the "primary" routes and uses. Further, we note that some of the Problem Formulation drafts indicate that OPPT *will* evaluate the conditions of use that were covered in prior EPA assessments because the resulting risk evaluation "*will be more robust if the potential risks from these conditions of use are evaluated by applying standards and guidance under Amended TSCA*..." This contradictory approach needs resolution because currently, there could be an appearance of inconsistent application of standards without providing a sound rationale.
    - Excluding certain pathways in risk evaluation on a "case-by-case" basis is not protective of ***all*** human populations. PESS need to be considered even if exposures may be less common (i.e., not primary) because EPA is responsible for protecting the human health of ***all*** Americans, including subpopulations (Executive Order (E.O.) 13045 [[HYPERLINK "https://www.epa.gov/children/executive-order-13045-protection-children-environmental-health-risks-and-safety-risks"]]; EPA's Children's Health Risk Policy [[HYPERLINK "https://www.epa.gov/children/epas-policy-evaluating-risk-children"]]).
    - The rationale to exclude pathways based on laws and programs believed to provide adequate regulation is not convincing because many of the Federal regulatory programs are not regulatory by nature and/or may be based on out of date standards.
        - *Out of date:* For example, OSHA's workplace standards should be excluded from the list of other Federal environmental laws that adequately assess and manage risk for chemicals found in the workplace due to outdated assessments (e.g., perchloroethylene Problem Formulations [p. 95], the 1970 OSHA permissible exposure limit [PEL] is 100 ppm, which is 75 ppm higher (4x higher) than California's PEL of 25

ppm passed in 1988). These standards suggest that other federal laws may be outdated as well.

- *Incomplete coverage of exposure pathways and scenarios relevant to Amended TSCA:* Each of these other regulations and programs undoubtedly have a different purpose, scope, and status than TSCA. Please include the findings of OPPT's assessment of these other programs regarding whether TSCA's goals are adequately addressed by these other regulations. Some of these exposure pathways may be slipping between regulations.
- *Enforcement:* Many standards lack enforcements due to a lack of inspectors and understaffing in the office. From OSHA's website: "Federal OSHA is a small agency; with our state partners we have approximately 2,100 inspectors responsible for the health and safety of 130 million workers, employed at more than 8 million worksites around the nation — which translates to about one compliance officer for every 59,000 workers" [[HYPERLINK "https://www.osha.gov/oshstats/commonstats.html"]].

- The Problem Formulation drafts do not state how the other laws will adequately assess and manage exposures to potentially exposed and susceptible subpopulations (PESS). For example, under CAA, SDWA, CWA, and RCRA, how are PESS identified and protected? If other offices have not reviewed whether a chemical substance presents an unreasonable risk to PESS (due to greater exposure or greater susceptibility) prior to the Problem Formulations then there is no compliance with the requirements under amended TSCA. Documentation to support whether PESS are identified and included in their assessments is needed.

- **We recommend that OPPT communicates a transparent process for conducting the additional investigations of conditions of use, describe the uncertainty related to the information obtained (including sources and documentation), and request public comments.**
  - Decision making process and criteria for excluding a condition of use or exposure pathway from the conceptual models are needed for clarity and transparency.
    - Add a flow diagram for decision making to increase transparency and understanding especially for exposure pathways removed from the conceptual models.
    - Please define "de minimis exposures," "case by case basis," "fit for purpose," "sufficient basis," and "adequately assessed by another Agency" (Lautenberg Act, 2016; Procedures for Chemical Risk Evaluation Under the Amended TSCA, 2016).
    - Many of the Problem Formulations documents state that pathways that are excluded have been "adequately assessed" but a citation to the source of the analysis and how it was conducted is lacking. For example, EPA has removed from consideration "...certain activities, exposure pathways that

EPA has concluded ***do not warrant inclusion*** in the risk evaluation…" based on ***insufficient information following further investigations*** conducted during Problem Formulation. Please include the findings that led to these conclusions.

- Uncertainty in decisions: There is uncertainty in the investigations performed for the activities that EPA has removed from the risk evaluation. The Problem Formulation documents acknowledge that EPA has insufficient information to remove certain conditions of use - *"For example, for some activities which were listed as 'conditions of use' in the scope document,* ***EPA has insufficient information following the further investigations during Problem Formulation*** *to find they are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."* That uncertainty needs to be communicated effectively (as previously recommended by the NAS). Is the information obtained from the "investigations" of quality? If yes, why is it not sufficient? EPA should carry out the obligations under Amended TSCA by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as reliability, relevance and whether the methods utilized were reasonable and consistent during Problem Formulation, explaining any assumptions used and gaps, and discussing information provided by independent sources.

2. The removal of general population as a receptor group in the six amended TSCA risk assessments is not protective of children's health. The Lautenberg Act was designed to perform risk evaluation that would protect all populations, including potentially exposed and susceptible subpopulations. We recommend including general population exposures in the risk evaluations.

- The general population is the comparison group to determine potentially exposed or susceptible subpopulations (PESS) in risk evaluation. In amended TSCA, PESS is defined as "…a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, ***may be at greater risk than the general population*** of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." Sec. 3 [12]).
- General population exposures need to be captured to calculate the actual total exposure levels to the US population in the risk evaluations.
- The overlap between conceptual models for occupational workers, consumers, and the general population, needs to be captured and explicitly described. Without incorporating the fact that individuals can be part of 1, 2, or all 3 groups leads to an underestimate of exposure and potentially exposed subpopulations. Please indicate the relationships among the separate conceptual models (by receptor group) and how these relationships lead to evaluating aggregate exposures across conceptual models and consideration of potentially highly exposed populations. For example, pregnant female occupational workers and nonusers are expected to be exposed to a chemical in their workplace, as consumers, and as part of the general population; they and their fetus represent a subpopulation with greater exposure and susceptibility.

3. There is a lack of consideration of life stages and PESS considerations in the Problem Formulations.

- **We recommend providing a more complete picture of the available chemical-specific PESS information in Sections 2.3.5.4 and 2.4.2.3.** While some chemical-specific PESS information is provided in specific draft Problem Formulations (e.g., perchloroethylene), many do not include any chemical-specific PESS information. In Section 2.3.5.4, for example, we note that women of childbearing age (WOCBA) would be a PESS under "workers and occupational non-users" for all 6 TSCA chemicals. Further, for some chemicals (e.g., TCE, MC), previously published Scope documents and/or previously published EPA assessments include specific PESS information, and yet this information has not been included in the Problem Formulation documents. Chemical-specific PESS information is important for guiding the analysis of data under risk evaluation.
- **The interactions and integration between exposure and biological susceptibility factors is missing.** The interactions between exposure factors (including exposures within the same exposure pathway) and biological susceptibility factors need to be described. For example, an individual may have a polymorphism in important metabolizing enzymes leading to increased genetic susceptibility to the same exposures, or the life stage of an individual may represent a critical window during development during which the same exposure can lead to a greater adverse response.
- **There is a lack of consistency across documents when discussing chemical-specific biomonitoring measurements (Section 2.3.3).** Some documents include information about biomonitoring data, others don't; the level of detail varies tremendously. Teams should update the NHANES information for their chemical using the Fourth National Health and Nutrition Examination Survey (which was released last year) and verify some additional tables that were released during March 2018. The actual report from CDC should be cited and not previous assessments. When referencing CDC NHANES data, the most comprehensive language from the perchloroethylene document should be used as it discusses the sampling period of the chemical and the concentration trend over the timeframe of the data.
- **We recommend that the life stage specific approach in EPA's Framework for children's risk assessment be applied to the amended TSCA risk evaluations.**
    - **The conceptual models do not describe "exposed life stage(s)" as stated in the Introduction section and in section 2.5 of some of the Problem Formulations documents.** The current language, "exposed life-stage" implies that a life stage approach is being applied but is misleading and does not reflect the Agency's life stage approach to children's health risk assessment.
    - **We recommend utilizing the EPA life stage framework in the Analysis Plan:** OPPT needs to account for the potential exposures to environmental agents during all stages of development, and consider all relevant adverse health outcomes that may result from such exposures. The life stage approach described in EPA's *Framework for Assessing Health Risk of Environmental Exposures to Children* (EPA, 2006) ensures a comprehensive evaluation of the

data through the lens of vulnerability and exposure throughout the life stages. Section 2.6.1 describes "age-specific differences" (exposure factors and activity patterns) that could be considered when there is "...reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further refined." The "age-specific factors" approach is limited in scope and in applicability, particularly when identifying the most vulnerable based on windows of greatest susceptibility as well as windows of highest exposure.

1,4-DIOXANE COMMENTS:

- **Water should be considered a pathway of exposure for 1,4-dioxane.**

P. 12 – Federal Laws and Regulations P. 65, Appendix A.1 – SDWA	None of the statues listed for SDWA regulate 1,4-dioxane. They only identify it as a hazard and monitor the chemical. Therefore, SDWA is not a strong enough argument to exclude water from exposure analysis and should not be taken out of the consumer model.
P. 29 – Presence in the Environment and Biota	High levels of 1,4-dioxane have been reported in groundwater in multiple states. OPPT states that "these data provide a basis for including groundwater in the scope" of risk evaluation. This logic should also carry over to the Problem Formulation for considering 1,4-dioxane in drinking water exposure.
P. 32 – Consumer Exposures & General Population Exposures	These sections are only one sentence long and does not mention that PESS is part of general population. There are multiple ways listed in which the general population could be exposed to 1,4-dioxane that are not listed in the conceptual model. Why?
P. 33 – PESS under Exposures P. 37 – PESS under Human Hazards	EO 13045 is not mentioned. Women of child bearing age, children, the elderly, and pregnant should also be mentioned. In general, language from the Perchloroethylene document's PESS section should be taken and inserted in this section as Perchloroehtylene's section is much more comprehensive.
P. 39 – Oral	The general population can be exposed through water by drinking contaminated water and may be exposed through inhalation of mist through showers.
P. 41 – Figure 2-2	By the definition provided in footnote b, fugitive emissions are emissions that include "equipment leaks from valves, pump seals, flanges, compressors, sampling connections, open-ended lines, evaporative losses from surface impoundment and spills, and releases from building ventilation systems". OPPT acknowledges that manufacturing is not a perfect, closed loop process and that accidental emissions will occur. The same is true for water contamination. 1,4-dioxane has the potential of polluting nearby waterways through leaks, spills, and accidental releases. Therefore, water contamination should be included in the conceptual model.
P. 42 – Section 2.5.3.1	Environmental release and waste pathways for the general population should be included in further analysis for water. See reasoning in previous comment (p. 41 – Figure 2-2).
P. 44 – Drinking Water Pathway	EPA's health advisories are non-enforceable and non-regulatory. Having a NPDWS for 1,4-dioxane does NOT fulfill the requirement for 1,4-dioxane already being regulated in water. Presently 1,4-dioxane is only monitored by UMCR 3 and is only being considered on CCL 4 and may not be ultimately regulated since CCL 4 is still a preliminary stage before Regulatory Determination 4 occurs within the OW. Therefore, OPPT has the responsibility for addressing 1,4-dioxane's route of exposure in water through TSCA.
P. 44 – Ambient Water Pathways	The document states that "EPA has not developed CWA section 304(a) recommended water quality criteria for the protection of aquatic life for

	1,4-dioxane". Therefore, OPPT has the opportunity through TSCA to work with OW to create a standard that addresses protecting aquatic life and how that affects human health as well. Since women of child bearing age, pregnant women, and lactating women are encouraged to eat diets high in fish, this investigation is especially important to mothers and children.

- **Conceptual models have removed multiple exposure pathways and receptors since those in the scoping document.**

P. 41 – Figure 2-2	Why have fugitive emissions been kept, but stack emissions removed?
p. 42 – Aquatic pathways	Not further analyzing ecological pathways is detrimental to health, especially for women of child bearing age, pregnant, and lactating mothers since they are advised to eat diets high in fish. If these fish are contaminated with 1,4-dioxane, they and their children will be at higher risk for toxicity.
P. 28 – Releases to the Environment P. 43 – Land-Applied Biosolids Pathway	More than half (52%) of 1,4-dioxane disposal went to land disposal. However, land-applied biosolids pathway will not be included in further risk analysis.
P. 47 – Figure 2-3	What is the purpose of this figure if many exposure pathways, receptors, and hazards are missing? This figure is missing almost the entirety of what was present in the original conceptual model in the scoping document (p. 38, Figure 2.3). The general population (PESS) have been removed. What will be assessed?
P. 48 – Exposure	EPA does not plan to further analyze background levels for ambient air, indoor air, groundwater, and drinking water. Even if these levels are small, they are more significant to children who have different behaviors and physiology that make them more susceptible to high exposures through these pathways. Therefore, it is important to consider these background quantities in conducting risk evaluation.
P. 49 – Exposure	EPA not further analyzing environmental fate or exposure is not protecting of PESS.
P. 51 – General Population	EPA should be analyzing general population exposures. Not doing so is not protecting PESS or the general public.
P. 52 - #3	Discussion of applicability of the Supplemental Cancer Guidelines and age-dependent adjustment factors needs to be included.

PERCHLOROETHYLENE COMMENTS:

- **Multiple exposure pathways, conditions of use, and receptors have been removed since those in the scoping document without adequate justification.**

P. 21 – Identification of Conditions of Use	What criteria is OPPT using to determine what constitutes "insufficient information" or "insignificant risks"? Even if a chemical is used in a closed system, contamination may still occur. As detailed later in the document, children may be exposed if take home exposure occurs from contaminated clothing.
P. 43 – Inhalation	Occupational non-users do not directly handle perchloroethylene, but the chemical may leak into locations where these workers sit if the factory is not properly sealed. What building codes exist that regulate perchloroethylene? If none cover the chemical, inhalation is a direct pathway that occupational non-users may be exposed.
P. 45 – Oral P. 57 – Oral	Why are bystanders not expected to be exposed to mists? Mists can diffuse nearby to consumers and bystanders. Fugitive emissions are possible.
P. 45 – Oral	Infants and young children may also be exposed to dust contaminated with perchloroethylene. Please include dust in the inhalation and oral pathways in this section and specifically how children's mouthing (as already mentioned) and crawling behaviors could increase exposure levels.
P. 46 – Dermal	Suggest adding a sentence stating that children are at greater risk for dermal exposure since their skin is more permeable and they have a greater surface area to volume ratio than adults. In addition, they are more likely to ingest water when bathing or swimming.
P. 41 – Figure 2-2	This version of the conceptual model has removed a large portion of what was previously included in the scoping documents. Why are co-located residences removed? Why has fugitive emissions been kept, but stack emissions removed?
P. 58 – Figure 2-3	This version of the conceptual model has removed a large portion of what was previously included in the scoping documents. Why are the exposure routes now more specific? Why is vapor, liquid contact missing?
P. 62 – Biosolids Pathways	Why is the biosolids pathways removed if a completed risk assessment has not been completed? Please clarify if EPA already has plans to start a risk assessment. If not, would completing the risk assessment under TSCA speed up this process?
P. 62 – Disposal Pathways	How is CAA section 129 enforced? If enforcement does not occur, could TSCA regulation better set limits that reduce perchloroethylene exposure?
P. 62 – Figure 2-4	There is no linkage between releases and hazards. Please explain.
P. 69 - #5	Supplemental Cancer Guidelines needs to be included under considerations.

METHYLENE CHLORIDE:

- **Potential pathways of exposure in human exposure section 2.3.5.3 have been excluded since the Scoping document without adequate rationale for their removal.**

P. 39 section 2.3.5.3	Please provide rationale for why the oral pathway of exposure from ingestion of residues on hands and body is no longer being considered for consumer populations (it was included in the Scoping document). Please explain why this pathway is included for general population but not for consumers who would be expected to have greater direct contact with MC-containing products.
P. 40 section 2.3.5.3	Dermal contact with contaminated water is included in scoping for general population, but it is not mentioned here. Please add this pathway back or provide rationale for exclusion.
P. 40 section 2.3.5.3	Oral ingestion of oysters and clams are mentioned as a potential source of exposure for general population in the scoping document, and is cited in an ATSDR report. However, there is no mention of this in the Problem Formulation document.
P. 46 Section 2.4.2.2	The IRIS MC assessment is cited stating that MC acts via a mutagenic mode of action. The 2005 Supplemental Cancer Guidelines provide evidence that early life stages are inherently more susceptible to carcinogens that action via the MOA, thus early life stages need to be included in this section as recommended by Agency guidance.

- **Conceptual models have significant changes with inconsistent rationale for excluding pathways**

P. 48 section 2.5.1 and Figure 2-2	There is not an explanation of why stack emissions are no longer being included in the conceptual model. This is a major change as it can be an additional source of potential MC exposure. If its exclusion is due to CAA then this needs to be explicitly stated for transparency and consistency.
P. 49 and 50 sections 2.5.1 and 2.5.2	There is a great example of scientific rationale for exclusion of a pathway of exposure for concurrent inhalation and dermal exposures that may occur via vapors on the skin. This level of detail and citation of the available science should be used when proposing to exclude any other pathway, when possible.
P. 57 CM 2-4	The conceptual model for environmental release has been significantly altered from the Scoping document's conceptual model and no longer includes exposure pathways from solid waste, liquid waste, or emissions to the air based on coverage under other Federal environmental regulations. However, these other programs do not necessarily consider the entire risk cup for the general population as they set standards for emissions (CAA) or waste releases (RCRA, CWA, SDWA) without taking into consideration the general population MC exposure levels from other media. They are therefore not being protective of this population. The exclusion of these pathways needs further explanation (i.e. review of the risk assessments supporting the MACTs for CAA, effluent limits for CWA, etc.) and should include the risk characterizations from the regulatory actions that are providing coverage (e.g. hazard index for MC across it's MACT categories) to transparently demonstrate that these other federal environmental laws are

	truly going to be protective for a receptor group that 1) is exposed via many pathways and 2) includes susceptible subgroups such as children who are often more sensitive to the effects environmental exposure due to physiological and behavioral factors and may not necessarily be statutorily required to be considered under these other laws.

- **Given the hazard profile of MC it is particularly concerning that general population has been removed for assessment as it is often the group in which exposures to infants and children are assessed.**

P. 62 section 2.6.1.4	The omission of assessment of risk to the general population is especially concerning for MC as it is 1) neurotoxic, which is an endpoint that developing children are often more sensitive to than adults and may result in more permanent damage as the neurological system is not fully formed, and 2) mutagenic which has been stated by the Agency as being potentially more concerning to early life stages as exposure to mutagens disproportionately increases the risk of cancer for those exposed during early life stages. See 2005 Supplemental Cancer Guidance and the 1998 Guidelines for Neurotoxicity Risk Assessment.
P. 66 section 2.6.2.2 #3	Supplemental Cancer Guidelines should be cited and a discussion of consideration of age-dependent adjustment factors should be included under # 3.

TRICHLOROETHYLENE COMMENTS:

- **General population should be assessed as a receptor group. There is not clear description about how other Federal environmental laws are ensuring the protection of the general population. In some instances, TCE has not been adequately assessed under these regulations for many years. More documentation is needed regarding the coverage from other laws specifically for TCE. The current language indicates an assumption that other laws protect the general public but instead may be leaving gaps in protection for general population.**

P. 27, Figure 2-1. TCE Life Cycle Diagram	General Population needs to be added to the header "Industrial, Commercial, Consumer Uses" because this figure is placed prior to the discussion about excluding ambient air TCE exposures to Gen Pop. The life cycle diagram should include all possible receptors.
P. 36, section 2.3.5.3	The last sentence in the section on "dermal" needs a citation. What physical and chemical properties would lead to "most" of the TCE being volatilized? Could provide a quantitative percentage that is volatilized? An analysis to understand the time by which volatilization would be complete in children is needed. Children have a greater surface area/volume ratio and therefore, dermal absorption would be expected to be greater than for an adult. Also, they have a smaller body weight than adults so a dermally applied dose would be expected to lead to a greater internal dose.
P. 51, section 2.5.3.3	There are issues excluding general population exposure pathways: ▪ Ambient air: MACTs are revised when the current standard is not shown to be protective enough and this has already happened (see 2007 final rule for halogenated cleaners). New hazard information has been released since 2007 and the IRIS program developed an assessment based on that data in 2011. The hazard indices calculated to support the 2007 MACT need to be updated to reflect this new information and properly reflect the risk to the general population. ▪ Ambient air: TCE is under multiple MACT categories, and therefore, EPA may be underestimating the risk to populations near TCE facilities. Given that TCE is addressed under the HAP program, it needs to be clearly stated the approaches taken by OAR to assess this type of risk. ▪ Drinking water: TCE is also regulated under SDWA, but in the second 6-year review completed in 2010 it was found to be a candidate for revision and underwent public comment. HoHHowever, OW has not taken any action to revise TCE. Why is OPPT stating that this chemical is adequately regulated by OW when there has not been a revision since 2010? Furthermore, TCE is no longer being considered for review in the 3rd 6-year cycle as it has "Recently Completed, Ongoing, or Pending Regulatory Action." Is OW agreeing to take action and revise TCE? OPPT needs to clarify that: 1) this ongoing regulatory action is not TSCA related, and 2) include the pathway in risk evaluation for further analysis until this can be sorted out. IF

	there is a concern with publicly stating what OW is doing with TCE (regulatory actions and current analysis/activities), then the agency needs to state in the document that this pathway will be included in the risk evaluation until there is a clear understanding of the current/potential OW activities.

- **Conceptual model is inconsistent with scoping models and exclusion of some pathways need to be adequately addressed and justified (e.g., with references, analysis exercises).**

P. 18, section 2.2.2.1	Need to add rationale/justification for the exclusion of conditions of use that were included in the Scope document. • 2.2.2.1: "EPA no longer believes that paints and coatings use contain TCE as evidenced by SNUR on TCE for Certain Consumer Products." "Believe" is not the appropriate word here; replace with "EPA has found evidence that…" OPPT should cite proper information from the SNUR as well as scientific citations of a study of TCE in paints and coatings.
P. 45, section 2.5.1	Need to add justification (citation to data, assessment, or other publication source), preferably quantitative, for the following statements: • "Generally, occupational non-users would not be expected to have dermal contact with liquid TCE…" • "…an insignificant fraction of the mist that deposits in the upper respiratory tract is expected to be available to be swallowed."
P. 46, CM 2-2 for industrial and commercial uses	Need to add justification and documentation of the exclusion of "indoor vapor in co-located residences and/or businesses." It was removed from the conceptual model and not readdressed in any way in the Problem Formulation.
P. 47, section 2.5.2	Even though inhalation was established as the primary route of exposure (RoE), that is not adequate justification for eliminating inclusion of other secondary or tertiary ROEs. Need citation to data/reference, assessment, or other publication source, preferably quantitative, for the following statements: • Dermal: "Generally, individuals that have contact with liquid TCE would be users and not bystanders." • Oral: "However, based on physical chemical properties, mists of TCE are expected to be rapidly absorbed in the respiratory tract or evaporate…"

- **Add appropriate language to the potentially exposed or susceptible subpopulations section describing greater potential susceptibility due to their greater exposure.**

P. 37, section 2.3.5.4	Add one bullet: • Individuals with unique activity patterns or behaviors leading to greater TCE exposure. For example, infants and toddlers drink more water/body weight and have greater hand to mouth and soil

	ingestion than adults. Other increased exposures could result from specific cultural practices such as a higher intake of fish in the diet.
P. 37, section 2.3.5.4	Revise the language of the first bullet as the fetus is also an exposed life stage for pregnant women workers: "Workers and occupational non-users, including **pregnant women, the fetuses of pregnant women, and** childbearing age (who may become pregnant)."

- **There is available TCE-specific information about potentially exposed and susceptible subpopulations and this information needs to be included in the exposure and hazard sections, and the analysis plan.**

P. 38, section 2.3.5.4	• Include an example of how the behavior of children may put them in closer contact to some consumer sources of TCE. Although the amount of TCE children may ingest through water varies, children tend to consume more water and food per body weight relative to adults, and have greater skin surface area than adults, relative to weight, which can result in proportionally higher ingestion and dermal exposures. The language from the perchloroethylene document should be used as an example as it is the most comprehensive. • Add that TCE exposures via all routes of exposure and pathways need to be considered for susceptible subpopulations as the TCE total exposure should be quantified as it will lead to greater risks.
P. 43, section 2.4.2.3	• Add TCE-specific information to this section. The reproductive and developmental toxicity of TCE should be included here as justification for indicating that susceptible subpopulations include the fetus, infants, and children. Data on skin sensitization, allergies, neurotoxicity, and immunotoxicity justify the inclusion of children and adults with pre-existing asthma, allergies, contact dermatitis, and immune deficiencies as susceptible subpopulations.
P. 57-59, section 2.6.1.5	• In the introduction, add a statement about workers and occupational non-users as potentially exposed or susceptible subpopulations due to their greater TCE exposure. • Bystanders are experiencing indoor exposures in the home to current regulated uses of TCE. Yet, take home exposures from workers are not being considered in the analysis and therefore, will underestimate bystander's risks. Add a bullet explaining how take-home exposures will be assessed using information from the scientific literature (i.e., residues from the workplace transported to the home via clothing or the body, exposing adults and children in their residences). • Since workers may live nearby the facility, they may also be exposed to higher ambient air levels of TCE as well. Explain how susceptible subpopulations in buildings co-located with facilities using TCE will be assessed. • Add a bullet to evaluate the data on the scenario of workers and occupational non-users who are women of child-bearing age (who may become pregnant) and pregnant women and their fetuses. This

	analysis should include a determination of the exposure levels relative to the IRIS RfD based on developmental effects (EPA, 2011).
P. 60, 2.6.1.6	#6: See edits: • First sentence: change "may be" to "will be" • Add: "fetuses" before "children" in second sentence. • first bullet: Change "age" to "life stage" • Add a bullet for sex differences.
P. 62- Section 2.6.2 #2 and in section 2.4.2.3	Suggest adding a statement from the scoping document that OPPT will be reevaluating the potentially susceptible groups that were considered in the 2014 TSCA work plan assessment and the 2011 IRIS assessment. Language from scoping is pasted below: *The IRIS assessment for TCE indicates that there is some evidence that certain populations may be more susceptible to exposure to TCE and examined life stage, gender-specific, genetic variation, race/ethnicity, preexisting health status, lifestyle factors and nutrition status. However, the IRIS assessment concluded that except for toxicokinetic variability, there are inadequate chemical-specific data to quantify the degree of differential susceptibility due to such factors.* *As for toxicokinetic variability, increased enzymatic activity of cytochrome P450 2E1 (CYP2E1) and glutathione-S-transferase (GST) polymorphisms may influence TCE susceptibility due to effects on the production of toxic metabolites (U.S. EPA, 2011). In the 2014 risk assessment (U.S. EPA, 2014b), EPA performed a population analysis to systematically estimate uncertainty and variability including human variability related to glutathione conjugation as a result of GST activity, which resulted in a distribution of human equivalent concentrations (HEC) for each endpoint. HEC99 values representing the most sensitive 1% of the population, a susceptible subpopulation, were used for risk evaluation, and EPA expects to perform a similar analysis for this assessment.*

- **There are available methodologies to assess dermal exposures that can be applied.**

P. 63, section 2.6.2.2, #6	Agree, if sufficient dermal toxicity studies are not identified in the literature search or in timely manner to assess risks from dermal exposures, then a route-to-route extrapolation from the inhalation and oral toxicity studies need to be conducted to assess systemic risks from dermal exposures. However, the lack of PBPK modeling is not a justification to disregard the TCE dermal assessment. An alternative approach is to perform dermal screening level assessments used by OPP.

ASBESTOS COMMENTS:

Recommend including specific conditions of use, exposure pathways, and human receptors. Recommend including more detailed chemical-specific PESS information.

P. 20, section 2.2.2.1	Legacy uses result in ongoing exposure to specific subpopulations leading to the greater exposure. To describe risks more accurately, EPA must also consider exposures from legacy uses as part of a comprehensive exposure assessment. These legacy uses are critical to account for because of their prevalence in the marketplace and risk factors germane in consumer products and materials, especially those impacting the health of pregnant woman and children (e.g., chemical residues found in children's products). Failure to include these exposure pathways will underestimate the total exposure for certain populations resulting in an incomplete characterization of potential risk.
P.29, section 2.3.2	NESHAPs promulgated under CCA and CERCLA control source/site specific emission management strategies, but there is available data that shows there are naturally occurring areas of higher airborne asbestos and hundreds of sites nationwide that would fall under legacy that have elevated levels. A consumer user or worker who also lived in these areas may have greater exposure compared to other susceptible subpopulations. NESHAPs are not considering all sources of asbestos and are therefore not protective.
P. 29, section 2.3.3	Given that asbestos is a naturally occurring mineral, the general population as well as workers are exposed to low levels of naturally occurring asbestos (ATSDR, 2001). Asbestos workers, including women of childbearing age, are exposed to low levels of asbestos in addition to their occupational exposure. Inaccurately assessing the natural background concentration of asbestos will underestimate the total exposure for certain populations during risk evaluation. Please add a discussion in section 2.3.3 about human monitoring measurements, which is consistent with the information provided in other PF documents.
P. 32, section 2.3.5.4	Add to following statement to the bullet to be consistent with other PF documents. "Workers and occupational non-users, **including women of childbearing age**."
P. 33, section 2.3.5.4	Include an example of how the behavior of children may put them in closer contact to some consumer sources of asbestos. Children have increased respiratory rates relative to adults and therefore may have increased exposures to asbestos.
P.35, section 2.4.2.2	Suggest adding language from the Scoping document. Language from scoping is pasted below: *Several assessments have identified populations that may potentially be susceptible to adverse health effects associated with asbestos exposure*

	(NTP, 2016; U.S. EPA, 2014; IARC, 2012; ATSDR, 2001). Numerous potential factors may contribute to increased susceptibility to asbestos including age, pre-existing health conditions, genetic makeup and co-exposure to other substances (e.g., tobacco smoke). Individuals exposed at an earlier age might be more susceptible to health effects due to the long-term retention of asbestos fibers in the lung and long latency period for the onset of asbestos-induced respiratory diseases (ATSDR, 2001). Smoking can impair clearance of particles like asbestos fibers from the respiratory track (U.S. EPA, 2014). Smokers who are also exposed to asbestos have increased risk of developing lung cancer than non-smokers, suggesting a synergistic relationship between cigarette smoking and asbestos exposure (NTP, 2016). Individuals with genetic polymorphisms or preexisting respiratory conditions may also experience altered biological response to asbestos) (U.S. EPA, 2014; IARC, 2012).
P. 50, section 2.6.1.4	The population most likely to have high exposure to asbestos are workers who come into contact with asbestos while on the job {ATSDR, 2001, 3098571}. Bystanders are experiencing indoor exposures in the home to current regulated uses of asbestos. Yet, take home exposures from workers are not being considered in the analysis and therefore, will underestimate bystander's risks. Add a bullet explaining how take-home exposures will be assessed using information from the scientific literature (i.e., residues from the workplace transported to the home via clothing or the body, exposing adults and children in their residences).

CARBON TETRACHLORIDE:

All available chemical-specific information about PESS needs to be included.

P. 38 Section 2.3.5.4	Add to following statement to the bullet to be consistent with other PF documents. "Workers and occupational non-users, **including women of childbearing age**."

TOXIC SUBSTANCES CONTROL ACT:
EPA IMPLEMENTATON ACTIVITIES AND PRIORITIZATION

Jeff Morris, Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
January 25, 2017

TSCA Amended

- The "Frank R. Lautenberg Chemical Safety for the 21st Century Act" signed June 22, 2016
- Amends and updates the Toxic Substances Control Act of 1976
- Passed by large bipartisan margins in the U.S. House (403 to 12) and unanimously in Senate
- Received support from chemical industry and downstream users of chemicals, NGOs and other stakeholders

Implementation: 1st year Key Milestones

- Final Active/Inactive **Inventory** Reporting Rule required by June 2017
  - ✓ Final Rule Published June 22, 2017
- Final **Prioritization** Process Rule required by June 2017
  - ✓ Final Rule Published June 22, 2017
- Final **Risk Evaluation** Rule required by June 2017
  - ✓ Final Rule Published June 22, 2017
- **Initial 10 Risk Evaluations**
  - ✓ Published First 10 Chemicals for Risk Evaluation
  - ✓ Final Scopes Published June 22, 2017
- **Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations under the Toxic Substances Control Act**
  - ✓ Guidance Published June 22, 2017
- **Science Advisory Committee** established by June 2017
  - ✓ Charter established, 18 members appointed

TSCA Implementation Milestones

By 2 Years (June 2018)

- ❑ Publish strategic plan for non-animal testing methodologies
- ❑ Finalize all necessary policies, procedures and guidance for TSCA implementation
- ❑ Publish guidance re: generic names for chem ID
- ❑ Receive active/inactive notices from manufacturers and processors (~Oct 2018) and update inventory listings (~Nov 2018)
- ❑ Propose rule for reviewing all chem ID claims (~Nov 2018)
- ❑ Propose rule for TSCA user fees (target date early 2018)

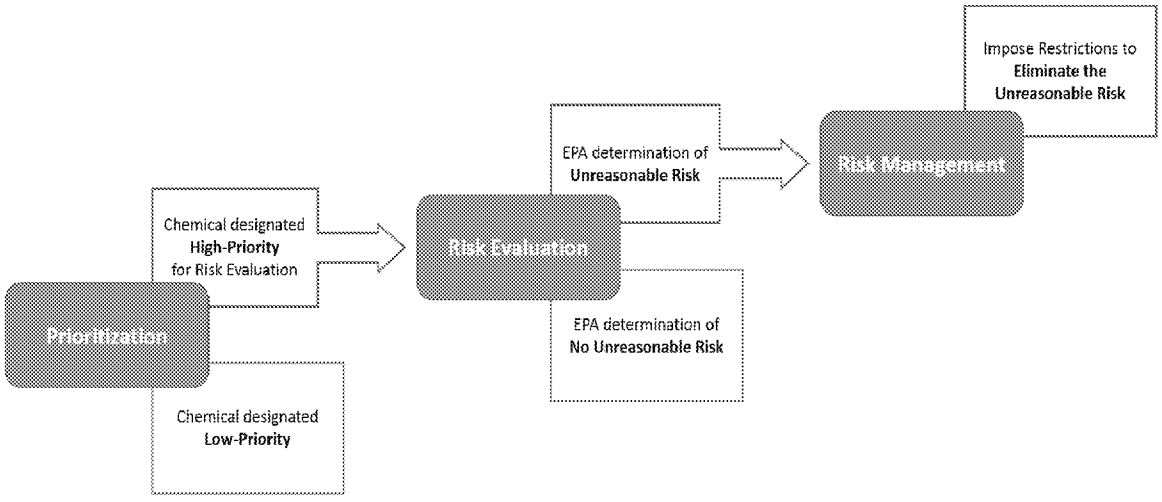
By 3.5 Years (late 2019)

- ❑ Finalize first 10 risk evaluations; initiate risk management if warranted
- ❑ Finalize rule for reviewing chem ID claims for active chems (~Nov 2019)
- ❑ Designate 20 High-Priority and 20 Low-Priority chemicals (~Dec 2019)
- ❑ Propose risk management rule for certain PBT chemicals (~Dec 2019)

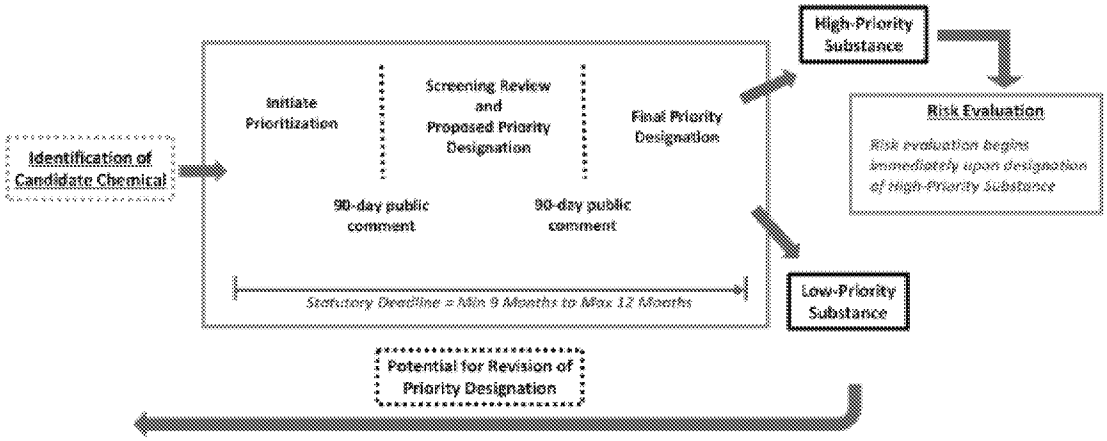
By 5 Years (June 2021)

- ❑ Complete review of CBI claims for chem ID
- ❑ Report to Congress on implementation of non-animal testing plan
- ❑ Finalize PBT rule (~December 2020)

New Process for Reviewing Existing Chemicals



Prioritization Process and Timeline



Next-steps: **Prioritization Process**

- Proposed rule included a ‘pre-prioritization’ process

- Final rule does not include the pre-prioritization process
  - However, EPA will take public comment opportunities to address pre-prioritization activities
  - *EPA held a public meeting December 2017.*

Risk Evaluation Process

- *High-priority* designation triggers risk evaluation process to be completed in 3 – 3.5 years
- For each risk evaluation completed, EPA must designate a new high-priority chemical
- Within 3.5 years, EPA must have EPA-initiated 20 ongoing chemical risk evaluations
    - Additional risk evaluations may come from manufacturer-requests

Initial 10 Risk Evaluations

Evaluations Initiated Dec. 19, 2016

1, 4 Dioxane
1-Bromopropane
Asbestos
Carbon Tetrachloride
Cyclic Aliphatic Bromide Cluster (HBCD)
Methylene Chloride
N-Methylpyrolidone
Pigment Violet 29
Trichloroethylene
Tetrachloroethylene

Initial 10 Risk Evaluations

- Scope documents published June 22, 2017
  - As required under section 6(b)(4)(D) EPA must publish a scope of the risk evaluation within 6 months of initiation.
  - Includes the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations that the Administrator expects to consider.
- Problem Formulation Documents in February 2018
  - These will further refine the scope, specifically the conditions of use considered in the risk evaluation

New Chemicals

- New law requires EPA to make an affirmative finding on new chemicals or significant new uses of existing chemicals, before those chemicals can enter the market
- Chemicals under review at time of enactment were considered “resubmitted” and review period restarted; additional notices continued to come in, resulting in the need to re-review
- Current focus is to improve processes to meet new requirements in law

Background

Presents an unreasonable risk

- Section 5(f) order
- Section 6(a) proposed rule
- Restriction/prohibition of manufacturing, processing, distribution, or disposal

Not likely to present an unreasonable risk

- Commercialization can commence after the determination is made
- Section 5(g) – Statement in the FR

Information is insufficient to permit a reasoned evaluation of the risk.

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required

Insufficient information to permit a reasoned evaluation **and may present** unreasonable risk

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required

For More Information

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act

Contact EPA at

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/forms/assessing-and-managing-chemicals-under-tsca

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families, et. al. on Proposed User Fees for the Administration of the Amended Toxic Substances Control Act

Submitted via Regulations.gov (May 24, 2018)

Docket ID EPA-HQ-OPPT-2016-0401

Introduction and Summary

These comments on EPA's proposed rule requiring user fees to support implementation of the Toxic Substances Control Act (TSCA) are submitted by Safer Chemicals Healthy Families (SCHF), Natural Resources Defense Council (NRDC), Earthjustice, Center for Environmental Health (CEH), and Environmental Health Strategy Center.[1] Our organizations are committed to assuring the safety of chemicals used in our homes, workplaces and in the many products to which our families and children are exposed each day.

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) which in key respects improves and strengthens TSCA, the nation's primary chemicals management law. The undersigned organizations took a leadership role during the LCSA legislative process, advocating the most protective legislation possible to reduce the risks of toxic chemicals in use today. We are now participating actively in all phases of LCSA implementation in order to better assure that the new law achieves its purpose of increasing evaluation, testing and regulation of chemicals that may pose unreasonable risks to human health and the environment.

In enacting LCSA, Congress recognized that effective implementation of the new law would require additional resources and that a significant portion of these increased costs should be underwritten by the regulated community. Section 26(b) of amended TSCA therefore imposes new requirements for the payment of "user fees" by manufacturers and processors subject to the Act. The goal of these requirements is to assure that 25 percent of the costs EPA incurs in carrying out sections 4, 5, 6 and 14 is contributed by industry.

EPA is facing a steadily increasing workload under TSCA in 2018 and later years and OPPT managers are already voicing concern about the "stresses" that resource limitations are placing on its ability to deliver on TSCA's mandates. Because of budget constraints, resources are being shifted to the TSCA program from other programs (like Safer Choice) essential to protecting public health, enabling sound purchasing decisions and encouraging innovation in green chemistries. These troubling developments underscore the importance of designing the TSCA fees rule to produce the maximum amount of revenue allowable under the law and establish an efficient and effective collection mechanism that prevents a shortfall in payments. The rule must also allocate responsibility for fees across industry in proportion to the relative contribution of specific chemicals to the potential risks EPA seeks to evaluate and manage under the law and the resource requirements for addressing these risks.

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[1] 83 Federal Register 8212 (Feb, 26, 2018)

We believe the February 26 proposal does not achieve these objectives and must be strengthened on several counts. As we discuss in these comments:

- Under the law, EPA must collect fees that defray 25 percent of the total costs of implementing section 4, 5 and 6 and processing CBI claims under section 14. The proposal estimates that these costs will be in the range of $80 million annually during FY 19-21 and therefore would require industry to pay fees of $20 million per year. We believe EPA has likely underestimated TSCA implementation costs significantly and that a more realistic analysis would require substantially larger industry fees.

- EPA has also likely underestimated the costs of conducting manufacturer-requested risk evaluations. The result may be that industry gets a "bargain" on these risk evaluations and that the taxpayer subsidizes them despite the intent of Congress to require industry to bear their costs. In addition, if EPA fails to recover all its costs, it could do a low-quality evaluation that is overly favorable to the chemical and its manufacturers in order to save money.

- According to the proposal, at industry's urging, the fees for section 4 testing orders, rules or consent agreements would be a small fraction of EPA's actual costs. This would create disincentives for EPA's use of section 4 because the Agency would have to absorb nearly all of the costs of issuing test rules, consent agreements and orders.

- EPA proposes that fees for PMNs will be the same regardless of the number of CBI claims made by the submitter. EPA should instead increase fees from the base level to reflect the number of CBI claims since these claims will add to the costs of reviewing the PMN. If submitters are charged for CBI claims, they will likely be more judicious in the claims they assert.

- Although the law requires EPA to allocate fees between manufacturers and processors, it proposes to assess fees only on manufacturers and to exempt processors. This will give processors a free ride even where their products (i.e. NMP and MC paint removers) account for a major portion of the risk attributable to a chemical.

- As the proposal is structured, a set fee will be assessed on manufacturers of chemicals undergoing risk evaluations, regardless of whether the chemical is determined to present an unreasonable risk. From a policy standpoint, such chemicals should be subject to an additional fee when they enter rulemaking under section 6(a) since the rulemaking will impose sizable additional costs on EPA directly related to the risks of the regulated chemical.

- EPA should rely on multiple sources in addition to CDR reports to identify companies obligated to pay fees. CDR requirements contain several exemptions and exclusions and compliance is uneven. Because CDR reports are submitted at four-year intervals, they may also lag in identifying changes in a chemical's manufacturers and importers. Unless EPA

accesses multiple databases, the universe of companies subject to fees will thus be incomplete and some manufacturers will avoid fee payments required by law.

- Although EPA says it intends to collect fees for activities occurring in FY19, its mechanism for fee collection would exempt manufacturers of the 10 chemicals subject to ongoing risk evaluations, despite the high costs these evaluations are placing on the Agency.

- EPA proposes to raise the revenue cap for small businesses to $91 million per year and then to reduce fees by 80 percent for all small businesses. This is an undue accommodation that fails to recognize that companies with revenues of this magnitude will in fact be able to afford the same fees as larger companies and in many cases may be a substantial manufacturer or processor of a chemical that presents significant risks.

- When EPA reviews fees in 2021, it should not simply make adjustments to account for inflation. Instead, to assure that it is complying with section 26(b), it must reexamine the costs of effective implementation of sections 4, 5, 6 and 14 and assess how well the current fee structure is performing in practice. This assessment may require changes in the fee rule to assure that it is actually recovering 25 percent of the Agency's costs, as required by section 26(b). EPA's review of the fees rule should engage all stakeholders, not just industry.

I. EPA's Proposal Underestimates Likely Costs of Implementing Sections 4, 5, 6 and 14 of TSCA

The law provides that EPA must collect fees that recover 25 percent of the total costs of implementing section 4, 5 and 6 and processing Confidential Business Information (CBI) claims under section 14. The EPA proposal projects that these costs will be $80.2 million per year and therefore would require industry to pay annual fees of $20.05 million. 83 Fed. Reg. 8216. Our analysis indicates that EPA has significantly underestimated likely TSCA implementation costs by failing to account fully for the activities and related expenditures necessary for effective implementation of the law. A more realistic and defensible projection of likely implementation costs would be above $100 million, resulting in greater user fee revenues and more EPA resources with which to accomplish the goals of the law and meet its requirements.

Examples of EPA's underestimation of likely implementation costs include the following:

- The Agency assumes that risk evaluations conducted under section 6(b) will cost an average of $3.9 million to complete. However, this assumption is based on the costs of risk assessments on Work Plan chemicals under the old law. 83 Fed. Reg. 8218-19. These assessments were narrow in scope, typically focusing on a few chemical uses and a subset of health and environmental end-points. Risk evaluations under the new law will be more comprehensive and encompass both a broader array of uses and the entire set of health and environmental effects attributable to the chemical. Thus, EPA will be required to obtain and examine much more toxicology and exposure data and conduct considerably more analysis. As a result, the costs per evaluation will be significantly higher than EPA assumes.

- EPA assumes that annual costs for risk management under section 6 will be $6,584,000. 83 Fed. Reg. 8219. Yet the Agency elsewhere indicates that the three section 6 rulemakings for Work Plan chemicals that EPA initiated under the new law have to date incurred average costs of $2,485,000 per chemical.[2] Because these rulemakings are not yet complete, their estimated costs are understated. Moreover, given the greater breadth of risk evaluations under section 6(b), subsequent section 6(a) rules are likely to encompass a wider range of uses and end-points than the Work Plan rulemakings, resulting in greater complexity and higher costs. For example, if seven of the 10 chemicals now being evaluated by EPA are determined to present unreasonable risks and rulemakings on these chemicals cost an average of $4 million, the resulting costs will likely substantially exceed its $6.5 estimate for all risk management activities under section 6. Moreover, over the next three years, EPA is required by section 6(h) to issue rules reducing exposure to five PBTs and is already is the process of collecting and analyzing data to support these rulemakings. These rulemakings will impose costs equal to if not greater than the costs of rulemakings resulting from the initial risk evaluations. Finally, EPA will continue to devote significant resources to implementing the PCB requirements in TSCA section 6(e) and, as section 6(a) rules become final, will incur costs to act on use exemptions under section 6(g).

- EPA estimates that prioritization under section 6(b) will cost $2,573,000 annually and require 5.1 Full Time Equivalents (FTEs).[3] These estimates greatly understate the level of effort necessary to comply with the requirements of the law. To identify prioritization candidates, EPA must screen a large number of chemicals, EPA must then designate at least 20 high-priority chemicals and 20 low-priority chemicals by the end of 2019 and will likely start evaluating an additional group of prioritization candidates in 2021. For each chemical, EPA must collect information on hazard and exposure from internal databases and public sources. Section 6(b)(1)(C) requires a 9-12 month prioritization process with two rounds of public comment. Thus, EPA will also need to review the information submitted by the public and respond to comments. Moreover, candidates for low-priority listing must be shown by sufficient information to lack the potential for unreasonable risk to health and the environment, requiring a comprehensive analysis of hazard, exposure and risk under the chemical's conditions of use. Assuming 20 high-priority and 20 low-priority designations, EPA's overall cost estimate for prioritization translates into a cost of $64,000 per priority listing, plainly well short of the resources required to complete the many steps in priority-setting under the law.

- EPA has reduced the total costs of reviewing premanufacture notices (PMNs) under section 5 by 20 percent to reflect an assumed decline in the number of PMN filings based on the increase in fees per submission. However, the only basis provided for the 20 percent reduction is EPA's estimate of a 10 percent decline in PMNs when it initially imposed fees on submitters in 1987. 83 Fed. Reg. 8226. EPA provides no retrospective analysis of the impact of the 1987 fees rules on the actual number of PMN submissions in subsequent years. Nor does it provide any economic rationale for why 20 percent of would-be submitters would decide against filing PMNs under the new fee rule. In the absence of a defensible rationale for assuming a decline in PMN filings, it would be imprudent to rely on this decline to lower

[2] EPA Technical Background Document for TSCA Fees, December 2017, at 3.
[3] Id. at 8.

the fees charged industry and jeopardize the Agency's ability to maximize recovery of its TSCA costs. Given EPA's projected cost of $55,343 per submission, if the number of PMNs did not decline but continued at 2016 levels in future years, EPA's annual section 5 review costs would be $6,353,060 more than estimated in its rule.

- Adding to this underestimate of the costs of section 5 implementation is EPA's assumption that development of section 5(e) orders and Significant New Use Rules (SNURs) will cost $1,648,162 and $1,552,609, respectively.[4] To date, EPA has issued 399 section 5(e) orders under the new law. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review This would translate into a per order cost of $4,130, an amount that would seem to greatly understate the time and effort required for order development. Moreover, under section 5(f)(4) of the new law, EPA must promulgate SNURs for all 5(e) chemicals or justify its decision not to do. Assuming SNURs are promulgated for 90 percent of section 5(e) orders, the costs per SNUR under EPA's analysis would be $4,374, likewise an absurdly low amount in light of the considerable level of effort required for SNUR rulemakings. Finally, EPA is planning a number of complex existing chemical SNURs (for example on PFAS substances and asbestos), but their costs do not appear to be reflected in EPA's calculation of section 5 implementation costs.

- EPA's calculation of section 4 costs assumes that EPA will issue 10 testing orders each year and one test rule and testing consent agreement every two years. 83 Fed. Reg. 8217. LCSA's streamlining of section 4 was intended to increase the amount of testing required under TSCA. We believe that EPA's assumed activity level under section 4 is much too low to meet Congressional expectations for a ramp up in data development under the law and that EPA's fee rule should plan for a significantly greater workload for testing orders, rules and consent agreements. In addition, EPA's cost estimates do not reflect the Agency's new responsibilities for implementing the animal testing provisions of section 4(h). The resources necessary to evaluate the reliability, relevance and equivalence of non-animal test methods in lieu of animal studies will be significant and should be factored into the calculation of section 4 implementation costs.

- EPA assumes that implementing the expanded CBI requirements in section 14 will cost $3,531,000 per year. 83 Fed. Reg. 8219. EPA has not provided a detailed explanation of this estimate. However, we believe it likely fails to reflect the significantly enhanced level of effort necessary to meet the new requirements. The higher level of activity under the new law likely means submission of more information by industry and a larger number of CBI claims. EPA must now require information submitters to substantiate most of their CBI claims. Thus, it must address what elements this substantiation must contain and review industry submissions to assure that it is provided. For the first time, all CBI claims for chemical identity and 25 percent of all other claims must be evaluated within 90 days and accepted or denied. CBI information can now be shared with states and health professionals. Moreover, since section 26(b) fees must cover CBI-related costs under all provisions of the statute, submissions under section 8, 12 and 13 must be considered in determining the level of fees required. Notably, the new law will greatly increase EPA's workload for CBI claims under both the Chemical Data Reporting (CDR) and the "active

[4] Id., at 7.

Inventory" reporting rules under section 8. Moreover, the CBI costs subject to fees include not just EPA staff involved in CBI reviews but the costs of establishing and updating CBI management and handling systems. To date, EPA has been swamped by the new CBI requirements and is struggling to carry out its increased responsibilities under 14. Meeting the law's requirements – which is essential for transparency and public access to data – will likely entail a much greater commitment of resources than the proposed rule assumes.

In finalizing its fees rule, EPA should reexamine these and other estimates of TSCA implementation costs. We believe that, properly quantified, these costs would likely exceed $100 million per year, perhaps significantly. More realistic estimates of the level of effort and funding required to successfully carry out the law will assure that industry makes the full contribution to EPA costs required by Congress and that a shortfall in fee revenues does not compromise effective TSCA implementation.

II. EPA Has Underestimated the Costs of Industry-Requested Risk Evaluations

EPA's proposed rule assumes that risk evaluations conducted in response to industry requests will cost $2.6 million, well below the $3.8 million projected for risk evaluations on high-priority chemicals. 83 Fed. Reg. 8219. To justify this lower number, EPA claims that because manufacturers must provide data on the chemical subject to their request, it will need to expend fewer resources on information collection to support these risk evaluations. Yet the provisions of its risk evaluation rule (40 C.F.R. 702.37) that EPA cites were in fact pared back significantly from the proposal and would limit the manufacturer's obligations to information on the specific uses it proposes for assessment and data in its immediate possession and control. Moreover, industry will have strong incentives to provide information on chemicals selected for evaluation by the Agency so it seems doubtful that the resource savings for industry-nominated chemicals would be significant. Nor is there any reason to believe – as EPA claims – that "manufacturers are more likely to request risk evaluations on chemicals that are low hazard or low exposure, or are otherwise relatively straightforward to analyze." Id. In fact, the opposite may be the case; industry may believe than an EPA assessment of a chemical of perceived concern will be more influential in the marketplace than any assessment it might conduct on its own.

For these reasons, EPA's rationale for assuming lower costs for manufacturer-requested evaluations is purely speculative. If it proves wrong in practice, the Agency would be forced to absorb substantial costs that Congress required industry to bear. EPA should assign the same costs to industry-requested evaluations that it assigns to evaluations of high-priority chemicals – and as shown above, the cost estimates for these evaluations in its proposal are understated and need to be adjusted upward.

III. There is No Legal or Policy Basis For Greatly Reducing Industry Fees for Section 4 Implementation

The proposed rule provides that fees for section 4 implementation would represent a minuscule share of EPA costs to develop and administer testing orders, rules and consent agreements. For example, EPA estimates costs of $279,000 per testing order but proposes to require fees of only

$9,800 (or 3.5 percent). 83 Fed. Reg. 8222. According to the proposed rule, EPA bases this approach on industry's strong opposition to paying fees for section 4 activities. 83 Fed. Reg. 8221. However, the proposal does not explain the rationale for industry's position or otherwise justify recovering a much smaller share of EPA costs under section 4 than under sections 5 and 6. Moreover, it is hard to square greatly reduced fees under section 4 with EPA's general recognition that it "should charge fees that are proportional to the EPA costs for undertaking the activities" which the fees will support. 83 Fed. Reg. 8215.

An unequal distribution of fees across EPA programs could have the perverse result of disincentivizing the Agency from implementing those aspects of TSCA that will receive the smallest share of fees, Thus, the Agency might well deemphasize activities (like issuing section 4 testing orders) that it must fund almost entirely from its own coffers and focus on those with a higher level of cost recovery. This could well inhibit use of the section 4 testing authorities, which EPA is already failing to utilize despite the new tools in the law to streamline testing requirements and increase development of data. We thus recommend that EPA increase fees for section 4 activities and support EPA's "Alternative A", which would bring these fees more in line with the fees for section 5 and 6 activities. See 83 Fed. Reg. 8223.

IV. Fees for Section 5 and Other Submissions Should Reflect the Number of CBI Claims Made by the Submitter

Section 26(b)(1) provides that one purpose of user fees is to "defray the cost of collecting, processing, reviewing and providing access to and protecting from disclosure" information that is subject to the confidentiality provisions of TSCA section 14. Nonetheless, EPA proposes that fees for PMNs and other submissions will be the same regardless of the number of CBI claims made by the submitter. 83 Fed. Reg. 8220. Given the additional time and effort EPA must expend to process CBI claims and safeguard CBI, there is no doubt that the costs it incurs to review PMNs and other submissions will vary in relation to whether the submitter seeks CBI protection for information in the submission and how many CBI claims it makes. Considering these costs in setting fee levels would thus help assure proportionality between fees and the Agency activities they support, consistent with the statutory goal of defraying the costs of implementing section 14 protections. It would also encourage submitters to exercise discipline in making CBI claims and reduce the number of claims that are unjustified: submitters will be less likely to make frivolous CBI claims if these claims result in increased fees.

We recommend that EPA develop a system of "surcharges" that are added to the base fees charged under section 5 and other TSCA provisions in proportion to the number of CBI claims that the submitter asserts.

V. EPA Should Not Fully Exempt Processors from Fee Obligations

Under its proposal, EPA has chosen to limit fee obligations under sections 4 and 6 to manufacturers/importers and to exempt processors. 83 Fed. Reg. 8216. This approach is contrary to TSCA section 26(b)(4)(C), which directs that EPA's fee rule must "reflect an appropriate balance in the assessment of fees between manufacturers and processors." There will be occasions where processing activities contribute significantly to the risks that EPA seeks to address under section 4

and 6; examples include the recent proposed section 6(a) rules for methylene chloride and N-methylpyrrolidone paint removers, which are formulated products that were put into the stream of commerce by processors. In these cases, processors should not get a free ride on TSCA implementation costs that are largely attributable to their products.

We agree with EPA that where a consortium is formed to assume responsibility for paying fees for a section 4 or section 6 activity, there would be no need for the Agency to require fee payments directly by processors. But if no consortium is formed or if a chemical's manufacturers are unwilling to cover required fees in their entirety and cannot reach a fee sharing agreement with processors, it would be prudent if EPA had the ability to assess fees on processors where appropriate. We recommend that the rule include a mechanism – to be triggered if necessary – by which significant processors can be identified and required to pay fees for section 4 and 6 activities. This mechanism would assure that EPA is not without recourse in those cases where processor fee payments are warranted for reasons of equity or to assure full recovery of the industry share of EPA's costs.

VI. EPA's Rule Should Require Additional Fee Payments Where a Chemical Advances to Section 6(a) Rulemaking after an Unreasonable Risk determination Under Section 6(b)

Under the rule as proposed, manufacturers of a chemical subject to a risk evaluation under section 6(b) would pay the same level of fees whether or not the evaluation results in a determination of unreasonable risk under section 6(b)(4)(A) that triggers rulemaking under section 6(a). EPA seeks comment in the proposal preamble on its "decision to not include a fee category for risk management under section 6(a)." 83 Fed. Reg. 8227.

Rulemaking under section 6(a) will incur significant costs in addition to those attributable to EPA's risk evaluation. Because these additional costs will be a function of EPA's determinations of unreasonable risk, it is appropriate to differentiate between chemicals that advance to risk management and those that are found not to pose an unreasonable risk following a risk evaluation. EPA's rule should recognize these differences: fees should be greater for chemicals that undergo rulemaking under section 6(a) because they pose higher risks and require a greater investment of Agency resources for risk management. This would follow the well-established principle that companies whose products contribute the most to endangering health or the environment should bear the largest share of the costs of protecting society from harm.

To implement this principle, EPA's rule should assess fees on manufacturers of high-priority chemicals at two action points under section 6. First, they should pay fees at the time a risk evaluation is initiated based on the costs of conducting that evaluation. Second, when EPA's evaluation concludes that a chemical presents an unreasonable risk of injury, manufacturers of that chemical should pay additional fees that reflect the costs of rulemaking and risk management under section 6(a).

VII. EPA Should Rely on Multiple Sources in addition to CDR Reports to Identify Companies Obligated to Pay Fees

The proposal preamble indicates that EPA plans to rely on reports filed under its Chemical Data Reporting (CDR) rule to identify manufacturers and importers subject to fees under sections 4 and

6. 83 Fed. 8216. We are concerned that this approach will be inadequate to identify the full universe of manufacturers and importers obligated to pay fees.

The CDR rule (40 C.F.R. Part 711) contains numerous exemptions from reporting for manufacturing activities and specific chemicals. It also applies only to persons manufacturing or importing a chemical at a single site during the principal reporting year in quantities of 25,000 pounds or above. Furthermore, our experience is that compliance with CDR requirements is uneven, particularly by importers of bulk chemical shipments or chemical-containing articles. And because CDR reporting is required at four year intervals, reports may not be current and up-to-date at the point in time where fees are payable. Thus, CDR reports will likely fail to provide a comprehensive picture of manufacturers and importers whose activities are significant, either because of the volumes they account for or their contribution to exposure and risk. This may not have practical consequences where a consortium of companies has agreed to pay the entire fee for a covered activity under sections 4 and 6. However, where a consortium is either not formed or is only prepared to pay a portion of the required fees, EPA's fee collections may fall short of the targets in its rule unless all manufacturers and importers of the subject chemical are known to the Agency and it has the means to compel compliance with fee obligations.

It is therefore essential for EPA to rely on a variety of databases to identify companies subject to fees. Reports under the "active" Inventory reporting rule, for example, would provide a more complete listing of current manufacturers and importers than CDR reports. Moreover, other databases like Panjiva comprehensively document import shipments and thus can be used to identify companies who failed to file reports under EPA rules. EPA should aggressively search these sources and then publish a preliminary list of manufacturers and importers responsible for paying fees with a request for additions to or deletions from the list. Although we agree that firms who fail to pay fees should be subject to sizable penalties, this may not be sufficient to assure a high level of compliance. Thus, EPA should also notify each known manufacturer and importer of its fee obligations.[5]

VIII. EPA Must Revise Its Rule to Assure that Manufacturers and Importers of the 10 Chemicals Now Undergoing Risk Evaluations are Subject to Fees

Under EPA's proposal, industry would begin to incur fee obligations on October 1, 2018, the start of FY19. 83 Fed. Reg. 8225. Since risk evaluations on the initial 10 chemicals will be underway throughout FY19 and into FY20, the costs of conducting these evaluations should thus be subject to fees. However, EPA's proposal also provides that the triggering event for fee payments for EPA-initiated risk evaluations will be the publication of the final risk evaluation scope. Scoping documents for the 10 chemicals were released in June 2017 (and may be modified in problem formulation documents that are expected shortly). Taken literally, this could mean that no fees are required for the ongoing risk evaluations because the scoping documents were finalized before October 1, 2018. However, this would be an untenable result that would deprive EPA of any cost recovery for activities that are plainly within the scope of fee requirements under TSCA section 26(b)(1). The resulting loss of revenues to EPA would be substantial: the proposal would require

[5] Where a consortium does not take responsibility for allocating fees among manufacturers and importers, EPA would have to make such an allocation itself in order to notify companies of the precise amounts they must pay. The proposed rule contemplates a *pro rata* division of fees, with each company paying the same amount, but this may not necessarily be the most equitable approach.

fees of $1,350,000 for each risk evaluation, totaling $13,500,000 for the 10 chemicals. To avoid lost revenues of this magnitude, EPA should revise the final rule so that it requires payment of fees for risk evaluations underway on October 1, 2018, notwithstanding the date of final scoping documents. Manufacturers and importers of the chemicals being evaluated should have 90 days to remit the applicable fees to the Agency.

IX. EPA's Proposal Provides Unjustified and Excessive Relief from Fees to "Small Businesses" as Defined in the Proposal

Although EPA is in the process of evaluating changes to its "small business" definition under TSCA section 8,[6] the proposed rule preempts this effort and grants broad relief to small businesses from fee obligations under section 26(b). 83 Fed. Reg. 8224. Under the proposal, the upper limit for small business status would be raised to $91 million in annual revenues from the current $40 million limit in the 1987 PMN fees rule. Applicability of this cutoff would be determined on the basis of average sales revenues over the three year period preceding a submission under section 4, 5 and 6 triggering fee payments. Once a manufacturer or importer qualifies as a small business under this standard, applicable fees would be reduced by 80 percent.

EPA explains that the new $91 million revenue cutoff is the result of adjusting the 1987 small business definition to account for inflation. 83 Fed. Reg. 8224. However, while changes in the Producer Price Index (PPI) are relevant, other factors are also important; these include "ability to pay," a consideration highlighted in section 26(b)(1)'s instructions to EPA on how to set fees. EPA has conducted no analysis demonstrating that the fee levels in its proposal will place hardships on businesses with annual revenues of $91 million or under.[7] Indeed, the proposed PMN fee of $16,000 represents .002 percent of EPA's proposed revenue cap, a *de minimis* amount for businesses of this size. Nor has EPA provided any basis for reducing fees payable by small businesses by 80 percent. There is no analysis, for example, indicating that a smaller fee reduction – say, 35 or 40 percent – would not be effective in cushioning small businesses from adverse financial impacts.

New chemicals commercialized by small businesses can result in significant PMN review costs where the new substance is to be produced in substantial volumes, will have substantial exposure or release or is likely to be toxic to humans or aquatic species. In such cases, a deep reduction in fees would fail to reflect the increased Agency resources required to review and manage the substance and its significant health or environmental footprint. A sliding scale for fees charged to small businesses that takes these factors into account would be better aligned with the purposes of section 26(b). As one approach, the 1988 small business standards under TSCA section 8 reflect a two-tier structure: a revenue cutoff of $40 million is used to define a small business except for chemicals produced in substantial quantities, to which a revenue limit of $4 million applies. 40 CFR 704.3 Following this approach, EPA's fee rule might include a lower revenue limit and/or a smaller

[6] 82 Fed. Reg. 56824 (November 30, 2017).

[7] While we oppose raising the revenue cap to $91 million per year, we believe annual revenues are a better measure of small business status than number of employees, an alternative approach that EPA is considering. 83 Fed. Reg. 8224. There is no meaningful correlation between a firm's ability to pay fees and the number of employees it has. For example, a U.S. importer of chemicals may have few employees because it is not engaged in manufacturing but could be distributing chemicals in this country in large volumes that support substantial fee payments.

fee reduction for chemicals produced in substantial quantities or with other characteristics indicative of potential exposure and hazard.

An 80 percent fee reduction would also be unjustified in the case where all manufacturers of a chemical selected for testing under section 4 or risk evaluation under section 6 are small businesses. 83 Fed. Reg. 8224. The effect of this fee reduction – which EPA's proposal would require – is that the Agency would recover only a small fraction of the costs it incurs in carrying out these actions. For example, small business fees for an EPA-initiated risk evaluation would only be $270,000, 7 percent of EPA's estimated costs for conducting the evaluation. Given that section 4 and section 6 actions apply to chemicals raising significant risk concerns, there is no policy or economic basis for providing small business relief to the companies responsible for their manufacture and distribution and shifting to EPA the bulk of the costs incurred to address and manage their risks. Thus, EPA should revise the final rule so that, where the only manufacturers/importers of chemicals subject to section 4 and 6 actions are small businesses, no fee reduction will be granted.

X. When EPA Reviews Fees in 2021, It Should Reexamine the Costs of Effective Implementation of Sections 4, 5, 6 and 14 and Assess How Well the Current Fee Structure is Working

Consistent with section 26(b), the proposed fee rule will only be in effect for FY2018-2021. Under section 26(b)(4)(E), EPA must increase or decrease fees every three years as necessary to adjust for inflation and to assure that the fees are sufficient to defray 25 percent of the costs of carrying out sections 4, 5, 6 and 14 of the Act. Despite this broad requirement, the proposed rule (83 Fed. Reg. 8231) suggests that, in 2021, EPA may only modify the fees in its rule to account for inflation and may consult only with industry about the need for further changes in the fee structure. We believe EPA should go further and commit to a full public review of the costs of implementing the law and the effectiveness of the rule in meeting statutory cost recovery targets.

The TSCA program will evolve significantly in the next few years and EPA will have actual data (as opposed to estimates) documenting its resource needs to meet its responsibilities under the law. It may turn out the scope of TSCA implementation activities is broader than EPA now envisions and that the resulting costs are significantly greater than EPA now assumes. (Indeed, as discussed above, we believe that the cost estimates in the proposed rule are likely understated by a substantial amount). It may also be the case that fee revenues under the rule are falling short of targets, requiring EPA to absorb more costs than the law requires, or that the current fee structure is having unintended consequences that detract from the law's policy goals. A full examination of these issues is necessary to assure that industry fees are in fact covering 25 percent of EPA's implementation costs and that the fee rule is operating effectively and efficiently. Engaging the public in this process is essential because of the importance of industry fees in fulfilling the risk prevention and reduction objectives of Congress.

We appreciate the opportunity to comment on the proposed fee rule and urge EPA to adopt our recommendations. Please contact Bob Sussman, SCHF counsel, with any questions or feedback at bobsussman1@comcast.net.

Respectfully submitted,

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EWG Comments on the Risk Evaluation Scoping for the First 10 Chemicals Under TSCA

Docket ID Nos.: EPA-HQ-OPPT-2016-0723 (1,4- Dioxane); EPA-HQ-OPPT-2016-0725 (Pigment Violent 29) EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene (also known as perchloroethylene)); EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride); EPA-HQ-OPPT-2016-0735 (Cyclic Aliphatic Bromide Cluster (HBCD)); EPA-HQ-OPPT-2016-0736 (Asbestos); EPA-HQ-OPPT-2016-0737 (Trichloroethylene (TCE)); EPA-HQ-OPPT-2016-0741 (1-Bromopropane); EPA-HQ-OPPT-2016-0742 (Methylene Chloride); and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone (NMP)).

The Environmental Working Group (EWG) is a nonprofit advocacy organization dedicated to improving environmental health. EWG has long advocated for stronger federal chemical regulations and spent over a decade advocating for reforms to strengthen the Toxic Substances Control Act (TSCA). The Frank R. Lautenberg Chemical Safety for the 21st Century Act (hereinafter "Lautenberg Act") for the first time will require the Environmental Protection Agency (EPA) to comprehensively review existing chemicals on the TSCA inventory—starting with 10 work plan chemicals, as required by section 6(b)(2)(A).[1] As the first chemicals assessed under the recently overhauled law, these first 10 assessments represent an early test of the strength of the new law. As such, it is important that the scopes of these first 10 chemical risk evaluations adequately consider the diverse uses of each chemical and the unique ways that vulnerable and chemically over-burdened populations may be at risk.

We submit these comments generally to apply to all 10 scoping documents released by EPA on June 22, 2017. The following comments are meant to assist EPA to strengthen the proposed scopes of the first 10 chemicals before it moves into the problem formulation phase of the risk evaluation process. In particular, EWG comments that EPA's scoping documents on the first 10 chemicals should be revised as needed to ensure they include:

- Reasonably foreseeable uses like accidents, misuses, and off-label uses
- The entire lifecycle of the chemical
- Exposures from non-TSCA uses
- Contaminants and low-concentration uses that contribute to overall exposure
- Exposures for which data is limited
- Risks to potentially exposed and susceptible populations
- Risks from aggregate and cumulative exposures

Accidents, misuses, and off-label uses

[1] 15 U.S.C. § 2605(b)(2)(A).

Pursuant to TSCA section 6(b)(4)(D), a chemical's scoping document should include "the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider."[2]

The Lautenberg Act defined "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[3] The plain language of this definition requires EPA to consider not only the intended and known uses of a chemical, but also any "reasonably foreseeable uses."

Reasonably foreseeable uses should include accidents like chemical spills and leaks that can contaminate air, water, and soil. The National Environmental Policy Act ("NEPA") highlights how "reasonable foreseeability" includes accidental releases in the context of environmental law. NEPA requires federal agencies to prepare an environmental impact statement ("EIS") for any proposed major federal action "significantly affecting the quality of the human environment."[4]

Other language in TSCA further underscores the intention to include accidental or inadvertent releases or exposures. The process for prioritizing chemicals requires EPA to consider "storage near significant sources of drinking water."[5] This is a clear reference to potential risks from accidental spills or leaks, or even criminal releases, into drinking water.

EWG is further concerned by EPA's stated intent to generally exclude "intentional misuses" from the scope of a chemical risk evaluation.[6] Reasonably foreseeable uses would also include foreseeable misuses, whether they are intentional or not. For example, a consumer may foreseeably misuse cleaning and other consumer products in several ways. A bathtub cleaner may also be used to clean the bathroom sink. A cleaner that is meant to be sprayed from 8 to 10 inches away may instead be sprayed from 3 inches away. Consumers and workers may apply more or less of a product than what is directed. Chemical facilities may intentionally improperly release or dispose of a chemical. These misuses are reasonably foreseeable and should be included in the scope of a risk evaluation.

Lifecycle of chemical, including legacy uses

Section 6(a) requires EPA to regulate when an unreasonable risk is posed by the "manufacture, processing, distribution in commerce, use, or disposal" of a chemical or "any combination such activities."[7] This makes clear that in the scope of a risk assessment, EPA must account for the entire lifecycle of the chemical, including risks during production, processing, distribution, recycling, and disposal, or any combination of those activities. It follows that the scope of EPA's risk evaluations should include both current and also legacy uses, as well as legacy disposal. As

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[2] 15 U.S.C. 2605 (b)(4)(D).
[3] 15 U.S.C. 2602(4).
[4] 42 U.S.C. § 4332(2)(C)(i).
[5] 15 U.S.C. § 2605(b)(1)(A).
[6] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).
[7] 15 U.S.C. 2605(a).

such, EWG is concerned by EPA's stated intention to focus on "uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal."[8]

This interpretation undermines the design of TSCA as a cradle-to-grave statute and is at odds with EPA's clear mandate to evaluate and regulate risks at the end of a chemical's lifecycle. Excluding legacy uses is also at odds with EPA's requirement to "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance."[9] To fully consider the frequency and number of exposures to a chemical, EPA must consider likely exposure from all sources—regardless of whether the exposure came from an ongoing or a legacy use.

Asbestos and the HBCD provide important examples. Both chemicals may be found in previously installed insulation and other building materials in homes, offices, schools and other buildings. They can be released if disturbed, creating an exposure risk. Thousands of American homes have asbestos-containing vermiculite insulation, and millions have HBCD-containing insulation board. As insulation ages, chemicals like HBCD and asbestos can migrate into household dust.

Building materials may also be improperly removed or disposed of, creating additional exposure risks. For example, in 2016, the Washington State Attorney General brought charges against a hotel owner for improper asbestos removal.[10] According to the news release, the owner lied about the extent of renovations in order to get around asbestos surveying and permit requirements. As a result, workers, inspectors, and people living near the hotel were all potentially exposed to unsafe levels of asbestos from legacy uses.

The prevalence of these legacy uses underscores the importance of including them in risk evaluations. Without considering exposure from legacy uses or disposal, EPA will be unable to assess the aggregate exposure because it will not have a complete picture of the "likely duration, intensity, frequency, and number of exposures to a chemical."

Consideration of non-TSCA uses

The requirement that EPA consider the "hazards, exposures, [and] conditions of use" in its scoping documents and also the "likely duration, intensity, frequency, and number of exposures" means that EPA must also consider uses covered by other agencies and statutes.

EWG is concerned by EPA's assertion that "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly

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[8] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017).
[9] 15 U.S.C. § 2605(b)(4)(F)(iv).
[10] Press Release, Washington State Office of the Attorney General, AG Files Criminal Charges Against Hotel Owner over Asbestos Removal (May 11, 2016), http://www.atg.wa.gov/news/news-releases/ag-files-criminal-charges-against-hotel-owner-over-asbestos-removal.

where the other agency has effectively managed the risks."[11] Even if another agency has taken steps to manage risk from a particular use, that doesn't mean the use does not contribute to exposure or that the risk has been eliminated. For example, many of the first 10 chemicals pose occupational risks that may be regulated by OSHA. However, oftentimes OSHA's regulations need to be updated or do not go far enough. For example, OSHA has a permissible exposure limit (PEL) for trichloroethylene, or TCE, but it is already 20 years old.[12] Additionally, even OSHA admits that many of its PELs are outdated and do not adequately protect workers from chemicals.[13] As such, action taken by OSHA should not be a basis for excluding occupational uses from a risk evaluation scope.

Likewise, several TSCA-regulated chemicals also have FDA-regulated uses. Although methylene chloride is primarily used as a paint stripper and remover,[14] FDA has also approved it as a food additive for uses including as a solvent in the extraction of caffeine from green coffee beans.[15] A person who uses a methylene chloride-based paint stripper may also drink decaffeinated coffee and could be exposed from both sources. 1,4-Dioxane, used industrially as a solvent and chemical stabilizer, is a well-known contaminant in personal care and other consumer products. A recent analysis by EWG found that as many as 8,000 personal care products contain ethoxylated ingredients manufactured through a process that may create 1,4-dioxane as a byproduct.[16] An individual exposed to 1,4-dioxane in an occupational setting would likely also be exposed to 1,4-dioxane through their personal care or cleaning products.

Finally, non-TSCA uses include uses regulated by EPA, but under other statutes. Several of the first 10 chemicals—including 1,4-dioxane, TCE, tetrachlorethylene (perc), methylene chloride, asbestos, and carbon tetrachloride—are known to contaminate drinking water systems, according to nationwide water testing results analyzed in EWG's recently released Tap Water Database.[17] These chemicals are detected in concentrations that exceed health guidelines in drinking water served to millions of Americans, sometimes in combination with each other due to a common industrial source. Of these contaminants, EPA has yet to set an enforceable drinking water standard for 1,4-dioxane. The Maximum Contaminant Levels set for carbon tetrachloride, TCE, tetrachlorethylene, and methylene chloride are all less health-protective than other standards or public health goals promulgated by EPA or other public health agencies such as the California Office of Environmental Health Hazard Assessment. Even so, EWG's analysis found drinking water violations in some drinking water systems that had levels of carbon tetrachloride, TCE,

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[11] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).

[12] Envtl. Protection Agency, Scope of the Risk Evaluation for Trichloroethylene, p. 32 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf

[13] U.S. Dep't of Labor, Occupational Safety and Health Administration, Permissible Exposure Limits—Annotated Tables, https://www.osha.gov/dsg/annotated-pels/ (last accessed Sept. 19, 2017).

[14] ATSDR, Toxicological Profile for Methylene Chloride, pp. 1-2, https://www.atsdr.cdc.gov/toxprofiles/tp14.pdf (last accessed March 7, 2017).

[15] 21 C.F.R. § 173.255(c).

[16] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

[17] Envtl. Working Grp., EWG's Tap Water Database, All Contaminants, https://www.ewg.org/tapwater/chemical-contaminants.php#.WcCifNN96CQ.

and tetrachlorethylene exceeding the MCLs. Because water contamination is so pervasive, and EPA's enforceable drinking water standards are often not sufficiently protective, EPA should always consider exposure from drinking water as part of its risk assessments.

These examples show that people are exposed to chemicals in myriad ways that often fall under the jurisdiction of different laws and different agencies. While EPA would only regulate some of those uses under TSCA, uses and exposures that occur outside of TSCA's jurisdiction contribute to an individual's aggregate exposure, and thus could contribute to an unreasonable risk of injury to health and must be considered.

Must be based on adequate information

EPA should not omit a condition of use from the scope of the risk assessment because data on that particular use is lacking. For example, EPA has insufficient information about the likely exposure of workers and people living in homes that use HBCD insulation. EPA also has limited information about 1,4-dioxane levels in products that contain ethoxylated ingredients. EPA should study exposures rather than make assumptions based on the limited data. After all, the law requires EPA to actively seek "reasonably available information" about conditions of use from stakeholders.[18]

"Reasonably available" is defined broadly in the final risk evaluation rule to include not only information EPA possesses, but also all information EPA can "reasonably generate, obtain, and synthesize for use in risk evaluations."[19] This would include information published in scientific journals and industry studies. It would also include information already collected by state governments or under foreign regulations like the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) in Europe. If EPA knows this information exists and was submitted to other governments, it should take measures to request the same information from the manufacturers or processors responsible for its submission. Additionally, EWG encourages EPA to rely on the appropriate use of defaults, or calculated uncertainty factors when specific information is missing. Finally, EPA has various tools under sections 4, 8(a), 8(c), 11 and 26(a) to order testing or solicit information as needed to fill data gaps.

Exposure from contaminants or impurities

EWG is concerned by EPA's stated intent to generally exclude impurities and other "de minimis" exposures from the scope of its risk evaluations.[20]

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[18] 15 U.S.C. § 2625(k) ("The Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator."); 15 § 2605(b)(4)(F)(i).

[19] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33748 (July 20, 2017) (to be codified at 40 C.F.R. pt. 702.33).

[20] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017)("EPA may choose not to include a particular impurity within the Scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the impurity would be 'de minimis' or otherwise insignificant.")

This general exclusion falsely equates de minimis exposures with low risk. It disregards the significant body of evidence that hormone disruptors and developmental toxicants may cause adverse effects at very low doses, and ignores the possibility of nonmonotonic dose-response curves. The pharmaceutical literature is rife with examples of nonmonotonicity, timing and age-group specific toxicity concerns.[21] Furthermore, even de minimis exposures contribute to an individual's aggregate exposure to a chemical.

An important example is 1,4-dioxane. 1,4-Dioxane is a well-known impurity that occurs as a byproduct of the ethoxylation process. In the scoping document for 1,4-dioxane, EPA has indicated it will exclude these uses from the scope of its evaluation. Specifically, EPA states that:

> In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane.[22]

This approach is backwards. 1,4-Dioxane is a likely carcinogen and is associated with several other health effects, including liver and kidney damage, lung irritation, and eye, nose, and throat irritation.[23] Whether the presence of 1,4-dioxane in a product is intentional or the result of contamination does not change the potential health risks. Furthermore, it makes more sense to examine the risks from 1,4-dioxane formation in the context of the risk evaluation on 1,4-dioxane when EPA will be looking at other routes of 1,4-dioxane exposure and specifically analyzing the risks from 1,4-dioxane.

Several chemicals form 1,4-dioxane as part of the ethoxylation process. An analysis of EWG's Skin Deep database found that as many as 8,000 products contained ethoxylated ingredients that create 1,4-dioxane as a byproduct during manufacturing.[24] Presumably, future EPA risk evaluations on any of those ethoxylated chemicals will be focused on the risks posed by those chemicals themselves, with 1,4-dioxane formation considered only as a secondary issue. Furthermore, evaluating 1,4-dioxane formation as part of the risk evaluation for each ethoxylated chemical separately—each of which could be years or decades apart—would give EPA a disjointed and incomplete picture of the real problem.

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[21] See, e.g., Non-monotonic Dose Response Curves, Our Stolen Future, http://www.ourstolenfuture.org/NewScience/lowdose/nonmonotonic.htm (last visited Sept. 19, 2017).
[22] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 8 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf (emphasis added).
[23] ATSDR, Toxicological Profile for 1,4-dioxane, Relevance to Public Health, p. 2, https://www.atsdr.cdc.gov/toxprofiles/tp187-c2.pdf (last accessed Sept. 19, 2017).
[24] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

As EPA admits,[25] there is little information about how widespread contamination from 1,4-dioxane is in consumer products with ethoxylated ingredients. Because it's not intentionally added it does not need to be listed on product labels, and companies are not required to measure or disclose levels of 1,4-dioxane in their products. As such, there is little way to know if 1,4-dioxane is present and, if so, at what levels. While manufacturers can take steps to minimize 1,4-dioxane formation or vacuum strip it from products, manufacturers are also not required to report if they are doing so.[26] EPA should not make assumptions based on what it does not know, but should instead study the issue.

Without more information, EPA cannot assume that 1,4-dioxane exposures through personal care and other consumer products are minimal and not a concern. Americans use several different kinds of personal care products every day, many of which contain ethoxylated ingredients and could be contaminated with 1,4-dioxane. It is reasonable to assume that many people exposed through their personal care products might also be exposed to 1,4-dioxane residues through cleaners, paints, dyes, or other consumer products. Those same individuals may also be exposed to 1,4-dioxane through drinking water, or may live in a community close to where 1,4-dioxane is processed, manufactured or disposed of. As such, even those "de minimis" exposures from 1,4-dioxane contamination can add up and contribute to an individual's aggregate exposure. Thus, these exposures should be included in the scope of risk evaluations so that EPA can more accurately gauge overall exposure and control risks.

Identifying hazards to "exposed individuals and populations"

EWG encourages EPA to keep in mind that the appropriate processes and procedures to identify susceptible and highly exposed populations may be unique to each substance evaluated. For example, legacy uses of a substance may have disproportionately contaminated particular communities, or exposure to a substance may pose unique health risks for fetal or childhood development. Consequently, EWG urges the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. EWG also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment.[27]

When EPA identifies "any potentially exposed or susceptible subpopulations" and "the hazards to health and the environment that EPA plans to evaluate," the agency should conduct outreach to communities likely to be home to potentially exposed or susceptible subpopulations. These communities may possess crucial information about hazards that the agency may itself lack. For

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[25] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 21 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf ("The extent that manufacturers or processors apply controls or processes to minimize or remove 1,4-dioxane in surfactants during manufacture or before formulation in consumer products is unknown and likely varies by sector.")

[26] *Id.*("manufacturers can apply controls to minimize the formation of 1,4-dioxane or remove most of the 1,4-dioxane present in these products through a vacuum stripping process").

[27] Envtl. Protection Agency, EJ 2020 Action Agenda: EPA's Environmental Justice Strategy, https://www.epa.gov/environmentaljustice/ej-2020-action-agenda-epas-environmental-justice-strategy (last visited Sept. 19, 2017).

example, as highlighted in the comments submitted by Earthjustice et al. in March,[28] such communities are in the best position to inform EPA about nursing homes or schools located near sites that increase the likelihood of their exposures to the chemical. Additionally, workers may be best able to identify real-world occupational exposures to chemicals, including roles and responsibilities that create highly exposed subgroups within their ranks. Other federal, state, and local regulatory authorities may also possess information necessary to establishing the proper scope of a risk assessment. For example, the California EPA has developed child-specific risk values for certain chemicals like atrazine and chlorpyrifos. Those values compare children's susceptibility to adults' by specifically examining child-specific routes of exposure.[29] EPA should review California EPA's approach and adopt its risk values as appropriate, and incorporate information from the analysis California EPA has already completed.

Aggregate and cumulative exposures

As part of a risk assessment, EPA is required to describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered.[30] As emphasized in the above sections, EWG strongly believes that considering the *aggregate* exposures will provide a more robust analysis of the total risk a chemical poses, and that EPA's scoping documents should reflect consideration of those aggregate exposures.

To properly assess aggregate exposures, EPA must consider exposures throughout the lifecycle of the chemical from all routes and pathways, including exposures from conditions of use not regulated by TSCA. This includes exposures from food, drinking water, pesticides, and personal care products, even if those uses are not specifically regulated during section 6(a) rulemaking. EWG emphasizes that this approach should include aggregate exposures from trace contaminants, such as asbestos fibers sometimes found in talc products,[31] or 1,4-dioxane in cleaning and personal care products that contain ethoxylated ingredients.[32]

When possible, EPA should also consider cumulative exposures when scoping a risk evaluation. EPA has explicit authority to order testing and prescribe protocols and methodologies for a number of health and environmental effects – including "cumulative or synergistic effects."[33] Considering cumulative exposures is in line with EPA's priorities and consistent with the best practices for risk evaluations. In *Framework for Cumulative Risk Assessment* (2003), EPA states,

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[28] Alaska Community Action on Toxics, et al., Comments on Scope of the Risk Evaluations for the First Ten Chemicals Under the Toxic Substances Control Act (Mar. 15, 2017).
[29] Cal. EPA, Office of Envtl. Health Hazard Assessment, Child-Specific Reference Doses Finalized to Date, http://oehha.ca.gov/risk-assessment/chrd/table-all-chrds (Jun. 22, 2010).
[30] 15 U.S.C. § 2605(b)(4)(F)(ii).
[31] Ronald Gordon, et. al., Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women, 20 Int'l J. of Occupational and Envt'l Health 318 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164883.
[32] Agency for Toxic Substances & Disease Registry, Public Health Statement for 1,4-Dioxane, Toxic Substances Portal (April 2012), https://www.atsdr.cdc.gov/phs/phs.asp?id=953&tid=199.
[33] 15 U.S.C. § 2603(b)(2)(A).

"Assessing cumulative risk through complex exposures is one of the Agency's high priorities…and it is germane and of great interest to all program and regional offices."[34]

Considering cumulative exposures is important because people and vulnerable subpopulations can be exposed to multiple chemicals and stressors that contribute to the same adverse health effects. The National Academy of Sciences (NAS) has noted the need to evaluate the cumulative effects of phthalates and also pointed to the fact that lead and mercury can collectively affect brain development.[35] Additionally, cumulative exposures to multiple carcinogenic solvents (TCE, 1,4-dioxane, methylene chloride and perchloroethylene) via air and drinking water may pose unique risks for people living near sites with industrial contamination. Taking such cumulative impacts into consideration would improve current assessments, and to the extent possible should be included in scoping.

EPA may consider collective exposure to groups of similar chemicals, and use the Adverse Outcome Pathway framework and database[36] to identify where cumulative effects may be an issue. EPA should follow the cumulative risk assessment process recommended by the National Academy of Sciences (NAS) in their Phthalates and Cumulative Risk Report.[37] When specific information is not available, EPA may use default values to account for cumulative exposures.

Conclusion

EWG appreciates the opportunity to comment on the scoping documents for the first 10 TSCA substances. We hope that these comments will help EPA to reevaluate the scoping documents of the first 10 TSCA substances so that they address fully the ways in which vulnerable and chemically over-burdened populations around the country are placed at risk by these chemicals. We look forward to continuing to participate in EPA's risk evaluation and risk management efforts under TSCA. Should you have any additional questions, please feel free to reach out to Melanie Benesh, Legislative Attorney at EWG, 202-939-0120, mbenesh@ewg.org.

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[34] Envtl. Protection Agency, Framework for Cumulative Risk Assessment, p. xi https://www.epa.gov/sites/production/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (last accessed Sept. 19, 2017).

[35] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508.

[36] Adverse Outcome Pathway Knowledge Database, Org. for Econ. Co-Operation & Dev., http://aopkb.org/ (last visited March 20, 2016).

[37] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508..

September 19, 2017

EWG Comments on the Risk Evaluation Scoping for the First 10 Chemicals Under TSCA

Docket ID Nos.: EPA-HQ-OPPT-2016-0723 (1,4- Dioxane); EPA-HQ-OPPT-2016-0725 (Pigment Violent 29) EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene (also known as perchloroethylene)); EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride); EPA-HQ-OPPT-2016-0735 (Cyclic Aliphatic Bromide Cluster (HBCD)); EPA-HQ-OPPT-2016-0736 (Asbestos); EPA-HQ-OPPT-2016-0737 (Trichloroethylene (TCE)); EPA-HQ-OPPT-2016-0741 (1-Bromopropane); EPA-HQ-OPPT-2016-0742 (Methylene Chloride); and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone (NMP)).

The Environmental Working Group (EWG) is a nonprofit advocacy organization dedicated to improving environmental health. EWG has long advocated for stronger federal chemical regulations and spent over a decade advocating for reforms to strengthen the Toxic Substances Control Act (TSCA). The Frank R. Lautenberg Chemical Safety for the 21st Century Act (hereinafter "Lautenberg Act") for the first time will require the Environmental Protection Agency (EPA) to comprehensively review existing chemicals on the TSCA inventory—starting with 10 work plan chemicals, as required by section 6(b)(2)(A).[1] As the first chemicals assessed under the recently overhauled law, these first 10 assessments represent an early test of the strength of the new law. As such, it is important that the scopes of these first 10 chemical risk evaluations adequately consider the diverse uses of each chemical and the unique ways that vulnerable and chemically over-burdened populations may be at risk.

We submit these comments generally to apply to all 10 scoping documents released by EPA on June 22, 2017. The following comments are meant to assist EPA to strengthen the proposed scopes of the first 10 chemicals before it moves into the problem formulation phase of the risk evaluation process. In particular, EWG comments that EPA's scoping documents on the first 10 chemicals should be revised as needed to ensure they include:

- Reasonably foreseeable uses like accidents, misuses, and off-label uses
- The entire lifecycle of the chemical
- Exposures from non-TSCA uses
- Contaminants and low-concentration uses that contribute to overall exposure
- Exposures for which data is limited
- Risks to potentially exposed and susceptible populations
- Risks from aggregate and cumulative exposures

Accidents, misuses, and off-label uses

[1] 15 U.S.C. § 2605(b)(2)(A).

Pursuant to TSCA section 6(b)(4)(D), a chemical's scoping document should include "the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider."[2]

The Lautenberg Act defined "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[3] The plain language of this definition requires EPA to consider not only the intended and known uses of a chemical, but also any "reasonably foreseeable uses."

Reasonably foreseeable uses should include accidents like chemical spills and leaks that can contaminate air, water, and soil. The National Environmental Policy Act ("NEPA") highlights how "reasonable foreseeability" includes accidental releases in the context of environmental law. NEPA requires federal agencies to prepare an environmental impact statement ("EIS") for any proposed major federal action "significantly affecting the quality of the human environment."[4]

Other language in TSCA further underscores the intention to include accidental or inadvertent releases or exposures. The process for prioritizing chemicals requires EPA to consider "storage near significant sources of drinking water."[5] This is a clear reference to potential risks from accidental spills or leaks, or even criminal releases, into drinking water.

EWG is further concerned by EPA's stated intent to generally exclude "intentional misuses" from the scope of a chemical risk evaluation.[6] Reasonably foreseeable uses would also include foreseeable misuses, whether they are intentional or not. For example, a consumer may foreseeably misuse cleaning and other consumer products in several ways. A bathtub cleaner may also be used to clean the bathroom sink. A cleaner that is meant to be sprayed from 8 to 10 inches away may instead be sprayed from 3 inches away. Consumers and workers may apply more or less of a product than what is directed. Chemical facilities may intentionally improperly release or dispose of a chemical. These misuses are reasonably foreseeable and should be included in the scope of a risk evaluation.

Lifecycle of chemical, including legacy uses

Section 6(a) requires EPA to regulate when an unreasonable risk is posed by the "manufacture, processing, distribution in commerce, use, or disposal" of a chemical or "any combination such activities."[7] This makes clear that in the scope of a risk assessment, EPA must account for the entire lifecycle of the chemical, including risks during production, processing, distribution, recycling, and disposal, or any combination of those activities. It follows that the scope of EPA's risk evaluations should include both current and also legacy uses, as well as legacy disposal. As

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[2] 15 U.S.C. 2605 (b)(4)(D).
[3] 15 U.S.C. 2602(4).
[4] 42 U.S.C. § 4332(2)(C)(i).
[5] 15 U.S.C. § 2605(b)(1)(A).
[6] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).
[7] 15 U.S.C. 2605(a).

such, EWG is concerned by EPA's stated intention to focus on "uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal."[8]

This interpretation undermines the design of TSCA as a cradle-to-grave statute and is at odds with EPA's clear mandate to evaluate and regulate risks at the end of a chemical's lifecycle. Excluding legacy uses is also at odds with EPA's requirement to "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance."[9] To fully consider the frequency and number of exposures to a chemical, EPA must consider likely exposure from all sources—regardless of whether the exposure came from an ongoing or a legacy use.

Asbestos and the HBCD provide important examples. Both chemicals may be found in previously installed insulation and other building materials in homes, offices, schools and other buildings. They can be released if disturbed, creating an exposure risk. Thousands of American homes have asbestos-containing vermiculite insulation, and millions have HBCD-containing insulation board. As insulation ages, chemicals like HBCD and asbestos can migrate into household dust.

Building materials may also be improperly removed or disposed of, creating additional exposure risks. For example, in 2016, the Washington State Attorney General brought charges against a hotel owner for improper asbestos removal.[10] According to the news release, the owner lied about the extent of renovations in order to get around asbestos surveying and permit requirements. As a result, workers, inspectors, and people living near the hotel were all potentially exposed to unsafe levels of asbestos from legacy uses.

The prevalence of these legacy uses underscores the importance of including them in risk evaluations. Without considering exposure from legacy uses or disposal, EPA will be unable to assess the aggregate exposure because it will not have a complete picture of the "likely duration, intensity, frequency, and number of exposures to a chemical."

Consideration of non-TSCA uses

The requirement that EPA consider the "hazards, exposures, [and] conditions of use" in its scoping documents and also the "likely duration, intensity, frequency, and number of exposures" means that EPA must also consider uses covered by other agencies and statutes.

EWG is concerned by EPA's assertion that "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly

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[8] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017).
[9] 15 U.S.C. § 2605(b)(4)(F)(iv).
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where the other agency has effectively managed the risks."[11] Even if another agency has taken steps to manage risk from a particular use, that doesn't mean the use does not contribute to exposure or that the risk has been eliminated. For example, many of the first 10 chemicals pose occupational risks that may be regulated by OSHA. However, oftentimes OSHA's regulations need to be updated or do not go far enough. For example, OSHA has a permissible exposure limit (PEL) for trichloroethylene, or TCE, but it is already 20 years old.[12] Additionally, even OSHA admits that many of its PELs are outdated and do not adequately protect workers from chemicals.[13] As such, action taken by OSHA should not be a basis for excluding occupational uses from a risk evaluation scope.

Likewise, several TSCA-regulated chemicals also have FDA-regulated uses. Although methylene chloride is primarily used as a paint stripper and remover,[14] FDA has also approved it as a food additive for uses including as a solvent in the extraction of caffeine from green coffee beans.[15] A person who uses a methylene chloride-based paint stripper may also drink decaffeinated coffee and could be exposed from both sources. 1,4-Dioxane, used industrially as a solvent and chemical stabilizer, is a well-known contaminant in personal care and other consumer products. A recent analysis by EWG found that as many as 8,000 personal care products contain ethoxylated ingredients manufactured through a process that may create 1,4-dioxane as a byproduct.[16] An individual exposed to 1,4-dioxane in an occupational setting would likely also be exposed to 1,4-dioxane through their personal care or cleaning products.

Finally, non-TSCA uses include uses regulated by EPA, but under other statutes. Several of the first 10 chemicals—including 1,4-dioxane, TCE, tetrachlorethylene (perc), methylene chloride, asbestos, and carbon tetrachloride—are known to contaminate drinking water systems, according to nationwide water testing results analyzed in EWG's recently released Tap Water Database.[17] These chemicals are detected in concentrations that exceed health guidelines in drinking water served to millions of Americans, sometimes in combination with each other due to a common industrial source. Of these contaminants, EPA has yet to set an enforceable drinking water standard for 1,4-dioxane. The Maximum Contaminant Levels set for carbon tetrachloride, TCE, tetrachlorethylene, and methylene chloride are all less health-protective than other standards or public health goals promulgated by EPA or other public health agencies such as the California Office of Environmental Health Hazard Assessment. Even so, EWG's analysis found drinking water violations in some drinking water systems that had levels of carbon tetrachloride, TCE,

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[13] U.S. Dep't of Labor, Occupational Safety and Health Administration, Permissible Exposure Limits—Annotated Tables, https://www.osha.gov/dsg/annotated-pels/ (last accessed Sept. 19, 2017).

[14] ATSDR, Toxicological Profile for Methylene Chloride, pp. 1-2, https://www.atsdr.cdc.gov/toxprofiles/tp14.pdf (last accessed March 7, 2017).

[15] 21 C.F.R. § 173.255(c).

[16] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

[17] Envtl. Working Grp., EWG's Tap Water Database, All Contaminants, https://www.ewg.org/tapwater/chemical-contaminants.php#.WcCifNN96CQ.

and tetrachlorethylene exceeding the MCLs. Because water contamination is so pervasive, and EPA's enforceable drinking water standards are often not sufficiently protective, EPA should always consider exposure from drinking water as part of its risk assessments.

These examples show that people are exposed to chemicals in myriad ways that often fall under the jurisdiction of different laws and different agencies. While EPA would only regulate some of those uses under TSCA, uses and exposures that occur outside of TSCA's jurisdiction contribute to an individual's aggregate exposure, and thus could contribute to an unreasonable risk of injury to health and must be considered.

Must be based on adequate information

EPA should not omit a condition of use from the scope of the risk assessment because data on that particular use is lacking. For example, EPA has insufficient information about the likely exposure of workers and people living in homes that use HBCD insulation. EPA also has limited information about 1,4-dioxane levels in products that contain ethoxylated ingredients. EPA should study exposures rather than make assumptions based on the limited data. After all, the law requires EPA to actively seek "reasonably available information" about conditions of use from stakeholders.[18]

"Reasonably available" is defined broadly in the final risk evaluation rule to include not only information EPA possesses, but also all information EPA can "reasonably generate, obtain, and synthesize for use in risk evaluations."[19] This would include information published in scientific journals and industry studies. It would also include information already collected by state governments or under foreign regulations like the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) in Europe. If EPA knows this information exists and was submitted to other governments, it should take measures to request the same information from the manufacturers or processors responsible for its submission. Additionally, EWG encourages EPA to rely on the appropriate use of defaults, or calculated uncertainty factors when specific information is missing. Finally, EPA has various tools under sections 4, 8(a), 8(c), 11 and 26(a) to order testing or solicit information as needed to fill data gaps.

Exposure from contaminants or impurities

EWG is concerned by EPA's stated intent to generally exclude impurities and other "de minimis" exposures from the scope of its risk evaluations.[20]

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[18] 15 U.S.C. § 2625(k) ("The Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator."); 15 § 2605(b)(4)(F)(i).

[19] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33748 (July 20, 2017) (to be codified at 40 C.F.R. pt. 702.33).

[20] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017)("EPA may choose not to include a particular impurity within the Scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the impurity would be 'de minimis' or otherwise insignificant.")

This general exclusion falsely equates de minimis exposures with low risk. It disregards the significant body of evidence that hormone disruptors and developmental toxicants may cause adverse effects at very low doses, and ignores the possibility of nonmonotonic dose-response curves. The pharmaceutical literature is rife with examples of nonmonotonicity, timing and age-group specific toxicity concerns.[21] Furthermore, even de minimis exposures contribute to an individual's aggregate exposure to a chemical.

An important example is 1,4-dioxane. 1,4-Dioxane is a well-known impurity that occurs as a byproduct of the ethoxylation process. In the scoping document for 1,4-dioxane, EPA has indicated it will exclude these uses from the scope of its evaluation. Specifically, EPA states that:

> In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane.[22]

This approach is backwards. 1,4-Dioxane is a likely carcinogen and is associated with several other health effects, including liver and kidney damage, lung irritation, and eye, nose, and throat irritation.[23] Whether the presence of 1,4-dioxane in a product is intentional or the result of contamination does not change the potential health risks. Furthermore, it makes more sense to examine the risks from 1,4-dioxane formation in the context of the risk evaluation on 1,4-dioxane when EPA will be looking at other routes of 1,4-dioxane exposure and specifically analyzing the risks from 1,4-dioxane.

Several chemicals form 1,4-dioxane as part of the ethoxylation process. An analysis of EWG's Skin Deep database found that as many as 8,000 products contained ethoxylated ingredients that create 1,4-dioxane as a byproduct during manufacturing.[24] Presumably, future EPA risk evaluations on any of those ethoxylated chemicals will be focused on the risks posed by those chemicals themselves, with 1,4-dioxane formation considered only as a secondary issue. Furthermore, evaluating 1,4-dioxane formation as part of the risk evaluation for each ethoxylated chemical separately—each of which could be years or decades apart—would give EPA a disjointed and incomplete picture of the real problem.

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[21] See, e.g., Non-monotonic Dose Response Curves, Our Stolen Future, http://www.ourstolenfuture.org/NewScience/lowdose/nonmonotonic.htm (last visited Sept. 19, 2017).
[22] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 8 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf (emphasis added).
[23] ATSDR, Toxicological Profile for 1,4-dioxane, Relevance to Public Health, p. 2, https://www.atsdr.cdc.gov/toxprofiles/tp187-c2.pdf (last accessed Sept. 19, 2017).
[24] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

As EPA admits,[25] there is little information about how widespread contamination from 1,4-dioxane is in consumer products with ethoxylated ingredients. Because it's not intentionally added it does not need to be listed on product labels, and companies are not required to measure or disclose levels of 1,4-dioxane in their products. As such, there is little way to know if 1,4-dioxane is present and, if so, at what levels. While manufacturers can take steps to minimize 1,4-dioxane formation or vacuum strip it from products, manufacturers are also not required to report if they are doing so.[26] EPA should not make assumptions based on what it does not know, but should instead study the issue.

Without more information, EPA cannot assume that 1,4-dioxane exposures through personal care and other consumer products are minimal and not a concern. Americans use several different kinds of personal care products every day, many of which contain ethoxylated ingredients and could be contaminated with 1,4-dioxane. It is reasonable to assume that many people exposed through their personal care products might also be exposed to 1,4-dioxane residues through cleaners, paints, dyes, or other consumer products. Those same individuals may also be exposed to 1,4-dioxane through drinking water, or may live in a community close to where 1,4-dioxane is processed, manufactured or disposed of. As such, even those "de minimis" exposures from 1,4-dioxane contamination can add up and contribute to an individual's aggregate exposure. Thus, these exposures should be included in the scope of risk evaluations so that EPA can more accurately gauge overall exposure and control risks.

Identifying hazards to "exposed individuals and populations"

EWG encourages EPA to keep in mind that the appropriate processes and procedures to identify susceptible and highly exposed populations may be unique to each substance evaluated. For example, legacy uses of a substance may have disproportionately contaminated particular communities, or exposure to a substance may pose unique health risks for fetal or childhood development. Consequently, EWG urges the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. EWG also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment.[27]

When EPA identifies "any potentially exposed or susceptible subpopulations" and "the hazards to health and the environment that EPA plans to evaluate," the agency should conduct outreach to communities likely to be home to potentially exposed or susceptible subpopulations. These communities may possess crucial information about hazards that the agency may itself lack. For

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[25] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 21 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf ("The extent that manufacturers or processors apply controls or processes to minimize or remove 1,4-dioxane in surfactants during manufacture or before formulation in consumer products is unknown and likely varies by sector.")

[26] *Id.*("manufacturers can apply controls to minimize the formation of 1,4-dioxane or remove most of the 1,4-dioxane present in these products through a vacuum stripping process").

[27] Envtl. Protection Agency, EJ 2020 Action Agenda: EPA's Environmental Justice Strategy, https://www.epa.gov/environmentaljustice/ej-2020-action-agenda-epas-environmental-justice-strategy (last visited Sept. 19, 2017).

example, as highlighted in the comments submitted by Earthjustice et al. in March,[28] such communities are in the best position to inform EPA about nursing homes or schools located near sites that increase the likelihood of their exposures to the chemical. Additionally, workers may be best able to identify real-world occupational exposures to chemicals, including roles and responsibilities that create highly exposed subgroups within their ranks. Other federal, state, and local regulatory authorities may also possess information necessary to establishing the proper scope of a risk assessment. For example, the California EPA has developed child-specific risk values for certain chemicals like atrazine and chlorpyrifos. Those values compare children's susceptibility to adults' by specifically examining child-specific routes of exposure.[29] EPA should review California EPA's approach and adopt its risk values as appropriate, and incorporate information from the analysis California EPA has already completed.

Aggregate and cumulative exposures

As part of a risk assessment, EPA is required to describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered.[30] As emphasized in the above sections, EWG strongly believes that considering the *aggregate* exposures will provide a more robust analysis of the total risk a chemical poses, and that EPA's scoping documents should reflect consideration of those aggregate exposures.

To properly assess aggregate exposures, EPA must consider exposures throughout the lifecycle of the chemical from all routes and pathways, including exposures from conditions of use not regulated by TSCA. This includes exposures from food, drinking water, pesticides, and personal care products, even if those uses are not specifically regulated during section 6(a) rulemaking. EWG emphasizes that this approach should include aggregate exposures from trace contaminants, such as asbestos fibers sometimes found in talc products,[31] or 1,4-dioxane in cleaning and personal care products that contain ethoxylated ingredients.[32]

When possible, EPA should also consider cumulative exposures when scoping a risk evaluation. EPA has explicit authority to order testing and prescribe protocols and methodologies for a number of health and environmental effects – including "cumulative or synergistic effects."[33] Considering cumulative exposures is in line with EPA's priorities and consistent with the best practices for risk evaluations. In *Framework for Cumulative Risk Assessment* (2003), EPA states,

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[28] Alaska Community Action on Toxics, et al., Comments on Scope of the Risk Evaluations for the First Ten Chemicals Under the Toxic Substances Control Act (Mar. 15, 2017).
[29] Cal. EPA, Office of Envtl. Health Hazard Assessment, Child-Specific Reference Doses Finalized to Date, http://oehha.ca.gov/risk-assessment/chrd/table-all-chrds (Jun. 22, 2010).
[30] 15 U.S.C. § 2605(b)(4)(F)(ii).
[31] Ronald Gordon, et. al., Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women, 20 Int'l J. of Occupational and Envt'l Health 318 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164883.
[32] Agency for Toxic Substances & Disease Registry, Public Health Statement for 1,4-Dioxane, Toxic Substances Portal (April 2012), https://www.atsdr.cdc.gov/phs/phs.asp?id=953&tid=199.
[33] 15 U.S.C. § 2603(b)(2)(A).

"Assessing cumulative risk through complex exposures is one of the Agency's high priorities…and it is germane and of great interest to all program and regional offices."[34]

Considering cumulative exposures is important because people and vulnerable subpopulations can be exposed to multiple chemicals and stressors that contribute to the same adverse health effects. The National Academy of Sciences (NAS) has noted the need to evaluate the cumulative effects of phthalates and also pointed to the fact that lead and mercury can collectively affect brain development.[35] Additionally, cumulative exposures to multiple carcinogenic solvents (TCE, 1,4-dioxane, methylene chloride and perchloroethylene) via air and drinking water may pose unique risks for people living near sites with industrial contamination. Taking such cumulative impacts into consideration would improve current assessments, and to the extent possible should be included in scoping.

EPA may consider collective exposure to groups of similar chemicals, and use the Adverse Outcome Pathway framework and database[36] to identify where cumulative effects may be an issue. EPA should follow the cumulative risk assessment process recommended by the National Academy of Sciences (NAS) in their Phthalates and Cumulative Risk Report.[37] When specific information is not available, EPA may use default values to account for cumulative exposures.

Conclusion

EWG appreciates the opportunity to comment on the scoping documents for the first 10 TSCA substances. We hope that these comments will help EPA to reevaluate the scoping documents of the first 10 TSCA substances so that they address fully the ways in which vulnerable and chemically over-burdened populations around the country are placed at risk by these chemicals. We look forward to continuing to participate in EPA's risk evaluation and risk management efforts under TSCA. Should you have any additional questions, please feel free to reach out to Melanie Benesh, Legislative Attorney at EWG, 202-939-0120, mbenesh@ewg.org.

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[34] Envtl. Protection Agency, Framework for Cumulative Risk Assessment, p. xi https://www.epa.gov/sites/production/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (last accessed Sept. 19, 2017).

[35] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508.

[36] Adverse Outcome Pathway Knowledge Database, Org. for Econ. Co-Operation & Dev., http://aopkb.org/ (last visited March 20, 2016).

[37] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508..

September 19, 2017

EWG Comments on the Risk Evaluation Scoping for the First 10 Chemicals Under TSCA

Docket ID Nos.: EPA-HQ-OPPT-2016-0723 (1,4- Dioxane); EPA-HQ-OPPT-2016-0725 (Pigment Violent 29) EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene (also known as perchloroethylene)); EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride); EPA-HQ-OPPT-2016-0735 (Cyclic Aliphatic Bromide Cluster (HBCD)); EPA-HQ-OPPT-2016-0736 (Asbestos); EPA-HQ-OPPT-2016-0737 (Trichloroethylene (TCE)); EPA-HQ-OPPT-2016-0741 (1-Bromopropane); EPA-HQ-OPPT-2016-0742 (Methylene Chloride); and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone (NMP)).

The Environmental Working Group (EWG) is a nonprofit advocacy organization dedicated to improving environmental health. EWG has long advocated for stronger federal chemical regulations and spent over a decade advocating for reforms to strengthen the Toxic Substances Control Act (TSCA). The Frank R. Lautenberg Chemical Safety for the 21st Century Act (hereinafter "Lautenberg Act") for the first time will require the Environmental Protection Agency (EPA) to comprehensively review existing chemicals on the TSCA inventory—starting with 10 work plan chemicals, as required by section 6(b)(2)(A).[1] As the first chemicals assessed under the recently overhauled law, these first 10 assessments represent an early test of the strength of the new law. As such, it is important that the scopes of these first 10 chemical risk evaluations adequately consider the diverse uses of each chemical and the unique ways that vulnerable and chemically over-burdened populations may be at risk.

We submit these comments generally to apply to all 10 scoping documents released by EPA on June 22, 2017. The following comments are meant to assist EPA to strengthen the proposed scopes of the first 10 chemicals before it moves into the problem formulation phase of the risk evaluation process. In particular, EWG comments that EPA's scoping documents on the first 10 chemicals should be revised as needed to ensure they include:

- Reasonably foreseeable uses like accidents, misuses, and off-label uses
- The entire lifecycle of the chemical
- Exposures from non-TSCA uses
- Contaminants and low-concentration uses that contribute to overall exposure
- Exposures for which data is limited
- Risks to potentially exposed and susceptible populations
- Risks from aggregate and cumulative exposures

Accidents, misuses, and off-label uses

[1] 15 U.S.C. § 2605(b)(2)(A).

Pursuant to TSCA section 6(b)(4)(D), a chemical's scoping document should include "the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider."[2]

The Lautenberg Act defined "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[3] The plain language of this definition requires EPA to consider not only the intended and known uses of a chemical, but also any "reasonably foreseeable uses."

Reasonably foreseeable uses should include accidents like chemical spills and leaks that can contaminate air, water, and soil. The National Environmental Policy Act ("NEPA") highlights how "reasonable foreseeability" includes accidental releases in the context of environmental law. NEPA requires federal agencies to prepare an environmental impact statement ("EIS") for any proposed major federal action "significantly affecting the quality of the human environment."[4]

Other language in TSCA further underscores the intention to include accidental or inadvertent releases or exposures. The process for prioritizing chemicals requires EPA to consider "storage near significant sources of drinking water."[5] This is a clear reference to potential risks from accidental spills or leaks, or even criminal releases, into drinking water.

EWG is further concerned by EPA's stated intent to generally exclude "intentional misuses" from the scope of a chemical risk evaluation.[6] Reasonably foreseeable uses would also include foreseeable misuses, whether they are intentional or not. For example, a consumer may foreseeably misuse cleaning and other consumer products in several ways. A bathtub cleaner may also be used to clean the bathroom sink. A cleaner that is meant to be sprayed from 8 to 10 inches away may instead be sprayed from 3 inches away. Consumers and workers may apply more or less of a product than what is directed. Chemical facilities may intentionally improperly release or dispose of a chemical. These misuses are reasonably foreseeable and should be included in the scope of a risk evaluation.

Lifecycle of chemical, including legacy uses

Section 6(a) requires EPA to regulate when an unreasonable risk is posed by the "manufacture, processing, distribution in commerce, use, or disposal" of a chemical or "any combination such activities."[7] This makes clear that in the scope of a risk assessment, EPA must account for the entire lifecycle of the chemical, including risks during production, processing, distribution, recycling, and disposal, or any combination of those activities. It follows that the scope of EPA's risk evaluations should include both current and also legacy uses, as well as legacy disposal. As

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[2] 15 U.S.C. 2605 (b)(4)(D).
[3] 15 U.S.C. 2602(4).
[4] 42 U.S.C. § 4332(2)(C)(i).
[5] 15 U.S.C. § 2605(b)(1)(A).
[6] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).
[7] 15 U.S.C. 2605(a).

such, EWG is concerned by EPA's stated intention to focus on "uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal."[8]

This interpretation undermines the design of TSCA as a cradle-to-grave statute and is at odds with EPA's clear mandate to evaluate and regulate risks at the end of a chemical's lifecycle. Excluding legacy uses is also at odds with EPA's requirement to "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance."[9] To fully consider the frequency and number of exposures to a chemical, EPA must consider likely exposure from all sources—regardless of whether the exposure came from an ongoing or a legacy use.

Asbestos and the HBCD provide important examples. Both chemicals may be found in previously installed insulation and other building materials in homes, offices, schools and other buildings. They can be released if disturbed, creating an exposure risk. Thousands of American homes have asbestos-containing vermiculite insulation, and millions have HBCD-containing insulation board. As insulation ages, chemicals like HBCD and asbestos can migrate into household dust.

Building materials may also be improperly removed or disposed of, creating additional exposure risks. For example, in 2016, the Washington State Attorney General brought charges against a hotel owner for improper asbestos removal.[10] According to the news release, the owner lied about the extent of renovations in order to get around asbestos surveying and permit requirements. As a result, workers, inspectors, and people living near the hotel were all potentially exposed to unsafe levels of asbestos from legacy uses.

The prevalence of these legacy uses underscores the importance of including them in risk evaluations. Without considering exposure from legacy uses or disposal, EPA will be unable to assess the aggregate exposure because it will not have a complete picture of the "likely duration, intensity, frequency, and number of exposures to a chemical."

Consideration of non-TSCA uses

The requirement that EPA consider the "hazards, exposures, [and] conditions of use" in its scoping documents and also the "likely duration, intensity, frequency, and number of exposures" means that EPA must also consider uses covered by other agencies and statutes.

EWG is concerned by EPA's assertion that "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly

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[8] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017).
[9] 15 U.S.C. § 2605(b)(4)(F)(iv).
[10] Press Release, Washington State Office of the Attorney General, AG Files Criminal Charges Against Hotel Owner over Asbestos Removal (May 11, 2016), http://www.atg.wa.gov/news/news-releases/ag-files-criminal-charges-against-hotel-owner-over-asbestos-removal.

where the other agency has effectively managed the risks."[11] Even if another agency has taken steps to manage risk from a particular use, that doesn't mean the use does not contribute to exposure or that the risk has been eliminated. For example, many of the first 10 chemicals pose occupational risks that may be regulated by OSHA. However, oftentimes OSHA's regulations need to be updated or do not go far enough. For example, OSHA has a permissible exposure limit (PEL) for trichloroethylene, or TCE, but it is already 20 years old.[12] Additionally, even OSHA admits that many of its PELs are outdated and do not adequately protect workers from chemicals.[13] As such, action taken by OSHA should not be a basis for excluding occupational uses from a risk evaluation scope.

Likewise, several TSCA-regulated chemicals also have FDA-regulated uses. Although methylene chloride is primarily used as a paint stripper and remover,[14] FDA has also approved it as a food additive for uses including as a solvent in the extraction of caffeine from green coffee beans.[15] A person who uses a methylene chloride-based paint stripper may also drink decaffeinated coffee and could be exposed from both sources. 1,4-Dioxane, used industrially as a solvent and chemical stabilizer, is a well-known contaminant in personal care and other consumer products. A recent analysis by EWG found that as many as 8,000 personal care products contain ethoxylated ingredients manufactured through a process that may create 1,4-dioxane as a byproduct.[16] An individual exposed to 1,4-dioxane in an occupational setting would likely also be exposed to 1,4-dioxane through their personal care or cleaning products.

Finally, non-TSCA uses include uses regulated by EPA, but under other statutes. Several of the first 10 chemicals—including 1,4-dioxane, TCE, tetrachlorethylene (perc), methylene chloride, asbestos, and carbon tetrachloride—are known to contaminate drinking water systems, according to nationwide water testing results analyzed in EWG's recently released Tap Water Database.[17] These chemicals are detected in concentrations that exceed health guidelines in drinking water served to millions of Americans, sometimes in combination with each other due to a common industrial source. Of these contaminants, EPA has yet to set an enforceable drinking water standard for 1,4-dioxane. The Maximum Contaminant Levels set for carbon tetrachloride, TCE, tetrachlorethylene, and methylene chloride are all less health-protective than other standards or public health goals promulgated by EPA or other public health agencies such as the California Office of Environmental Health Hazard Assessment. Even so, EWG's analysis found drinking water violations in some drinking water systems that had levels of carbon tetrachloride, TCE,

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[11] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).

[12] Envtl. Protection Agency, Scope of the Risk Evaluation for Trichloroethylene, p. 32 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf

[13] U.S. Dep't of Labor, Occupational Safety and Health Administration, Permissible Exposure Limits—Annotated Tables, https://www.osha.gov/dsg/annotated-pels/ (last accessed Sept. 19, 2017).

[14] ATSDR, Toxicological Profile for Methylene Chloride, pp. 1-2, https://www.atsdr.cdc.gov/toxprofiles/tp14.pdf (last accessed March 7, 2017).

[15] 21 C.F.R. § 173.255(c).

[16] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

[17] Envtl. Working Grp., EWG's Tap Water Database, All Contaminants, https://www.ewg.org/tapwater/chemical-contaminants.php#.WcCifNN96CQ.

and tetrachlorethylene exceeding the MCLs. Because water contamination is so pervasive, and EPA's enforceable drinking water standards are often not sufficiently protective, EPA should always consider exposure from drinking water as part of its risk assessments.

These examples show that people are exposed to chemicals in myriad ways that often fall under the jurisdiction of different laws and different agencies. While EPA would only regulate some of those uses under TSCA, uses and exposures that occur outside of TSCA's jurisdiction contribute to an individual's aggregate exposure, and thus could contribute to an unreasonable risk of injury to health and must be considered.

Must be based on adequate information

EPA should not omit a condition of use from the scope of the risk assessment because data on that particular use is lacking. For example, EPA has insufficient information about the likely exposure of workers and people living in homes that use HBCD insulation. EPA also has limited information about 1,4-dioxane levels in products that contain ethoxylated ingredients. EPA should study exposures rather than make assumptions based on the limited data. After all, the law requires EPA to actively seek "reasonably available information" about conditions of use from stakeholders.[18]

"Reasonably available" is defined broadly in the final risk evaluation rule to include not only information EPA possesses, but also all information EPA can "reasonably generate, obtain, and synthesize for use in risk evaluations."[19] This would include information published in scientific journals and industry studies. It would also include information already collected by state governments or under foreign regulations like the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) in Europe. If EPA knows this information exists and was submitted to other governments, it should take measures to request the same information from the manufacturers or processors responsible for its submission. Additionally, EWG encourages EPA to rely on the appropriate use of defaults, or calculated uncertainty factors when specific information is missing. Finally, EPA has various tools under sections 4, 8(a), 8(c), 11 and 26(a) to order testing or solicit information as needed to fill data gaps.

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This general exclusion falsely equates de minimis exposures with low risk. It disregards the significant body of evidence that hormone disruptors and developmental toxicants may cause adverse effects at very low doses, and ignores the possibility of nonmonotonic dose-response curves. The pharmaceutical literature is rife with examples of nonmonotonicity, timing and age-group specific toxicity concerns.[21] Furthermore, even de minimis exposures contribute to an individual's aggregate exposure to a chemical.

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This approach is backwards. 1,4-Dioxane is a likely carcinogen and is associated with several other health effects, including liver and kidney damage, lung irritation, and eye, nose, and throat irritation.[23] Whether the presence of 1,4-dioxane in a product is intentional or the result of contamination does not change the potential health risks. Furthermore, it makes more sense to examine the risks from 1,4-dioxane formation in the context of the risk evaluation on 1,4-dioxane when EPA will be looking at other routes of 1,4-dioxane exposure and specifically analyzing the risks from 1,4-dioxane.

Several chemicals form 1,4-dioxane as part of the ethoxylation process. An analysis of EWG's Skin Deep database found that as many as 8,000 products contained ethoxylated ingredients that create 1,4-dioxane as a byproduct during manufacturing.[24] Presumably, future EPA risk evaluations on any of those ethoxylated chemicals will be focused on the risks posed by those chemicals themselves, with 1,4-dioxane formation considered only as a secondary issue. Furthermore, evaluating 1,4-dioxane formation as part of the risk evaluation for each ethoxylated chemical separately—each of which could be years or decades apart—would give EPA a disjointed and incomplete picture of the real problem.

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[21] See, e.g., Non-monotonic Dose Response Curves, Our Stolen Future, http://www.ourstolenfuture.org/NewScience/lowdose/nonmonotonic.htm (last visited Sept. 19, 2017).
[22] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 8 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf (emphasis added).
[23] ATSDR, Toxicological Profile for 1,4-dioxane, Relevance to Public Health, p. 2, https://www.atsdr.cdc.gov/toxprofiles/tp187-c2.pdf (last accessed Sept. 19, 2017).
[24] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

As EPA admits,[25] there is little information about how widespread contamination from 1,4-dioxane is in consumer products with ethoxylated ingredients. Because it's not intentionally added it does not need to be listed on product labels, and companies are not required to measure or disclose levels of 1,4-dioxane in their products. As such, there is little way to know if 1,4-dioxane is present and, if so, at what levels. While manufacturers can take steps to minimize 1,4-dioxane formation or vacuum strip it from products, manufacturers are also not required to report if they are doing so.[26] EPA should not make assumptions based on what it does not know, but should instead study the issue.

Without more information, EPA cannot assume that 1,4-dioxane exposures through personal care and other consumer products are minimal and not a concern. Americans use several different kinds of personal care products every day, many of which contain ethoxylated ingredients and could be contaminated with 1,4-dioxane. It is reasonable to assume that many people exposed through their personal care products might also be exposed to 1,4-dioxane residues through cleaners, paints, dyes, or other consumer products. Those same individuals may also be exposed to 1,4-dioxane through drinking water, or may live in a community close to where 1,4-dioxane is processed, manufactured or disposed of. As such, even those "de minimis" exposures from 1,4-dioxane contamination can add up and contribute to an individual's aggregate exposure. Thus, these exposures should be included in the scope of risk evaluations so that EPA can more accurately gauge overall exposure and control risks.

Identifying hazards to "exposed individuals and populations"

EWG encourages EPA to keep in mind that the appropriate processes and procedures to identify susceptible and highly exposed populations may be unique to each substance evaluated. For example, legacy uses of a substance may have disproportionately contaminated particular communities, or exposure to a substance may pose unique health risks for fetal or childhood development. Consequently, EWG urges the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. EWG also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment.[27]

When EPA identifies "any potentially exposed or susceptible subpopulations" and "the hazards to health and the environment that EPA plans to evaluate," the agency should conduct outreach to communities likely to be home to potentially exposed or susceptible subpopulations. These communities may possess crucial information about hazards that the agency may itself lack. For

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[25] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 21 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf ("The extent that manufacturers or processors apply controls or processes to minimize or remove 1,4-dioxane in surfactants during manufacture or before formulation in consumer products is unknown and likely varies by sector.")

[26] *Id.*("manufacturers can apply controls to minimize the formation of 1,4-dioxane or remove most of the 1,4-dioxane present in these products through a vacuum stripping process").

[27] Envtl. Protection Agency, EJ 2020 Action Agenda: EPA's Environmental Justice Strategy, https://www.epa.gov/environmentaljustice/ej-2020-action-agenda-epas-environmental-justice-strategy (last visited Sept. 19, 2017).

example, as highlighted in the comments submitted by Earthjustice et al. in March,[28] such communities are in the best position to inform EPA about nursing homes or schools located near sites that increase the likelihood of their exposures to the chemical. Additionally, workers may be best able to identify real-world occupational exposures to chemicals, including roles and responsibilities that create highly exposed subgroups within their ranks. Other federal, state, and local regulatory authorities may also possess information necessary to establishing the proper scope of a risk assessment. For example, the California EPA has developed child-specific risk values for certain chemicals like atrazine and chlorpyrifos. Those values compare children's susceptibility to adults' by specifically examining child-specific routes of exposure.[29] EPA should review California EPA's approach and adopt its risk values as appropriate, and incorporate information from the analysis California EPA has already completed.

Aggregate and cumulative exposures

As part of a risk assessment, EPA is required to describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered.[30] As emphasized in the above sections, EWG strongly believes that considering the *aggregate* exposures will provide a more robust analysis of the total risk a chemical poses, and that EPA's scoping documents should reflect consideration of those aggregate exposures.

To properly assess aggregate exposures, EPA must consider exposures throughout the lifecycle of the chemical from all routes and pathways, including exposures from conditions of use not regulated by TSCA. This includes exposures from food, drinking water, pesticides, and personal care products, even if those uses are not specifically regulated during section 6(a) rulemaking. EWG emphasizes that this approach should include aggregate exposures from trace contaminants, such as asbestos fibers sometimes found in talc products,[31] or 1,4-dioxane in cleaning and personal care products that contain ethoxylated ingredients.[32]

When possible, EPA should also consider cumulative exposures when scoping a risk evaluation. EPA has explicit authority to order testing and prescribe protocols and methodologies for a number of health and environmental effects – including "cumulative or synergistic effects."[33] Considering cumulative exposures is in line with EPA's priorities and consistent with the best practices for risk evaluations. In *Framework for Cumulative Risk Assessment* (2003), EPA states,

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[28] Alaska Community Action on Toxics, et al., Comments on Scope of the Risk Evaluations for the First Ten Chemicals Under the Toxic Substances Control Act (Mar. 15, 2017).
[29] Cal. EPA, Office of Envtl. Health Hazard Assessment, Child-Specific Reference Doses Finalized to Date, http://oehha.ca.gov/risk-assessment/chrd/table-all-chrds (Jun. 22, 2010).
[30] 15 U.S.C. § 2605(b)(4)(F)(ii).
[31] Ronald Gordon, et. al., Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women, 20 Int'l J. of Occupational and Envt'l Health 318 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164883.
[32] Agency for Toxic Substances & Disease Registry, Public Health Statement for 1,4-Dioxane, Toxic Substances Portal (April 2012), https://www.atsdr.cdc.gov/phs/phs.asp?id=953&tid=199.
[33] 15 U.S.C. § 2603(b)(2)(A).

"Assessing cumulative risk through complex exposures is one of the Agency's high priorities…and it is germane and of great interest to all program and regional offices."[34]

Considering cumulative exposures is important because people and vulnerable subpopulations can be exposed to multiple chemicals and stressors that contribute to the same adverse health effects. The National Academy of Sciences (NAS) has noted the need to evaluate the cumulative effects of phthalates and also pointed to the fact that lead and mercury can collectively affect brain development.[35] Additionally, cumulative exposures to multiple carcinogenic solvents (TCE, 1,4-dioxane, methylene chloride and perchloroethylene) via air and drinking water may pose unique risks for people living near sites with industrial contamination. Taking such cumulative impacts into consideration would improve current assessments, and to the extent possible should be included in scoping.

EPA may consider collective exposure to groups of similar chemicals, and use the Adverse Outcome Pathway framework and database[36] to identify where cumulative effects may be an issue. EPA should follow the cumulative risk assessment process recommended by the National Academy of Sciences (NAS) in their Phthalates and Cumulative Risk Report.[37] When specific information is not available, EPA may use default values to account for cumulative exposures.

Conclusion

EWG appreciates the opportunity to comment on the scoping documents for the first 10 TSCA substances. We hope that these comments will help EPA to reevaluate the scoping documents of the first 10 TSCA substances so that they address fully the ways in which vulnerable and chemically over-burdened populations around the country are placed at risk by these chemicals. We look forward to continuing to participate in EPA's risk evaluation and risk management efforts under TSCA. Should you have any additional questions, please feel free to reach out to Melanie Benesh, Legislative Attorney at EWG, 202-939-0120, mbenesh@ewg.org.

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[34] Envtl. Protection Agency, Framework for Cumulative Risk Assessment, p. xi https://www.epa.gov/sites/production/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (last accessed Sept. 19, 2017).

[35] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508.

[36] Adverse Outcome Pathway Knowledge Database, Org. for Econ. Co-Operation & Dev., http://aopkb.org/ (last visited March 20, 2016).

[37] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508..

September 19, 2017

EWG Comments on the Risk Evaluation Scoping for the First 10 Chemicals Under TSCA

Docket ID Nos.: EPA-HQ-OPPT-2016-0723 (1,4- Dioxane); EPA-HQ-OPPT-2016-0725 (Pigment Violent 29) EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene (also known as perchloroethylene)); EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride); EPA-HQ-OPPT-2016-0735 (Cyclic Aliphatic Bromide Cluster (HBCD)); EPA-HQ-OPPT-2016-0736 (Asbestos); EPA-HQ-OPPT-2016-0737 (Trichloroethylene (TCE)); EPA-HQ-OPPT-2016-0741 (1-Bromopropane); EPA-HQ-OPPT-2016-0742 (Methylene Chloride); and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone (NMP)).

The Environmental Working Group (EWG) is a nonprofit advocacy organization dedicated to improving environmental health. EWG has long advocated for stronger federal chemical regulations and spent over a decade advocating for reforms to strengthen the Toxic Substances Control Act (TSCA). The Frank R. Lautenberg Chemical Safety for the 21st Century Act (hereinafter "Lautenberg Act") for the first time will require the Environmental Protection Agency (EPA) to comprehensively review existing chemicals on the TSCA inventory—starting with 10 work plan chemicals, as required by section 6(b)(2)(A).[1] As the first chemicals assessed under the recently overhauled law, these first 10 assessments represent an early test of the strength of the new law. As such, it is important that the scopes of these first 10 chemical risk evaluations adequately consider the diverse uses of each chemical and the unique ways that vulnerable and chemically over-burdened populations may be at risk.

We submit these comments generally to apply to all 10 scoping documents released by EPA on June 22, 2017. The following comments are meant to assist EPA to strengthen the proposed scopes of the first 10 chemicals before it moves into the problem formulation phase of the risk evaluation process. In particular, EWG comments that EPA's scoping documents on the first 10 chemicals should be revised as needed to ensure they include:

- Reasonably foreseeable uses like accidents, misuses, and off-label uses
- The entire lifecycle of the chemical
- Exposures from non-TSCA uses
- Contaminants and low-concentration uses that contribute to overall exposure
- Exposures for which data is limited
- Risks to potentially exposed and susceptible populations
- Risks from aggregate and cumulative exposures

Accidents, misuses, and off-label uses

[1] 15 U.S.C. § 2605(b)(2)(A).

Pursuant to TSCA section 6(b)(4)(D), a chemical's scoping document should include "the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider."[2]

The Lautenberg Act defined "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[3] The plain language of this definition requires EPA to consider not only the intended and known uses of a chemical, but also any "reasonably foreseeable uses."

Reasonably foreseeable uses should include accidents like chemical spills and leaks that can contaminate air, water, and soil. The National Environmental Policy Act ("NEPA") highlights how "reasonable foreseeability" includes accidental releases in the context of environmental law. NEPA requires federal agencies to prepare an environmental impact statement ("EIS") for any proposed major federal action "significantly affecting the quality of the human environment."[4]

Other language in TSCA further underscores the intention to include accidental or inadvertent releases or exposures. The process for prioritizing chemicals requires EPA to consider "storage near significant sources of drinking water."[5] This is a clear reference to potential risks from accidental spills or leaks, or even criminal releases, into drinking water.

EWG is further concerned by EPA's stated intent to generally exclude "intentional misuses" from the scope of a chemical risk evaluation.[6] Reasonably foreseeable uses would also include foreseeable misuses, whether they are intentional or not. For example, a consumer may foreseeably misuse cleaning and other consumer products in several ways. A bathtub cleaner may also be used to clean the bathroom sink. A cleaner that is meant to be sprayed from 8 to 10 inches away may instead be sprayed from 3 inches away. Consumers and workers may apply more or less of a product than what is directed. Chemical facilities may intentionally improperly release or dispose of a chemical. These misuses are reasonably foreseeable and should be included in the scope of a risk evaluation.

Lifecycle of chemical, including legacy uses

Section 6(a) requires EPA to regulate when an unreasonable risk is posed by the "manufacture, processing, distribution in commerce, use, or disposal" of a chemical or "any combination such activities."[7] This makes clear that in the scope of a risk assessment, EPA must account for the entire lifecycle of the chemical, including risks during production, processing, distribution, recycling, and disposal, or any combination of those activities. It follows that the scope of EPA's risk evaluations should include both current and also legacy uses, as well as legacy disposal. As

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[2] 15 U.S.C. 2605 (b)(4)(D).
[3] 15 U.S.C. 2602(4).
[4] 42 U.S.C. § 4332(2)(C)(i).
[5] 15 U.S.C. § 2605(b)(1)(A).
[6] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).
[7] 15 U.S.C. 2605(a).

such, EWG is concerned by EPA's stated intention to focus on "uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal."[8]

This interpretation undermines the design of TSCA as a cradle-to-grave statute and is at odds with EPA's clear mandate to evaluate and regulate risks at the end of a chemical's lifecycle. Excluding legacy uses is also at odds with EPA's requirement to "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance."[9] To fully consider the frequency and number of exposures to a chemical, EPA must consider likely exposure from all sources—regardless of whether the exposure came from an ongoing or a legacy use.

Asbestos and the HBCD provide important examples. Both chemicals may be found in previously installed insulation and other building materials in homes, offices, schools and other buildings. They can be released if disturbed, creating an exposure risk. Thousands of American homes have asbestos-containing vermiculite insulation, and millions have HBCD-containing insulation board. As insulation ages, chemicals like HBCD and asbestos can migrate into household dust.

Building materials may also be improperly removed or disposed of, creating additional exposure risks. For example, in 2016, the Washington State Attorney General brought charges against a hotel owner for improper asbestos removal.[10] According to the news release, the owner lied about the extent of renovations in order to get around asbestos surveying and permit requirements. As a result, workers, inspectors, and people living near the hotel were all potentially exposed to unsafe levels of asbestos from legacy uses.

The prevalence of these legacy uses underscores the importance of including them in risk evaluations. Without considering exposure from legacy uses or disposal, EPA will be unable to assess the aggregate exposure because it will not have a complete picture of the "likely duration, intensity, frequency, and number of exposures to a chemical."

Consideration of non-TSCA uses

The requirement that EPA consider the "hazards, exposures, [and] conditions of use" in its scoping documents and also the "likely duration, intensity, frequency, and number of exposures" means that EPA must also consider uses covered by other agencies and statutes.

EWG is concerned by EPA's assertion that "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly

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[8] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017).
[9] 15 U.S.C. § 2605(b)(4)(F)(iv).
[10] Press Release, Washington State Office of the Attorney General, AG Files Criminal Charges Against Hotel Owner over Asbestos Removal (May 11, 2016), http://www.atg.wa.gov/news/news-releases/ag-files-criminal-charges-against-hotel-owner-over-asbestos-removal.

where the other agency has effectively managed the risks."[11] Even if another agency has taken steps to manage risk from a particular use, that doesn't mean the use does not contribute to exposure or that the risk has been eliminated. For example, many of the first 10 chemicals pose occupational risks that may be regulated by OSHA. However, oftentimes OSHA's regulations need to be updated or do not go far enough. For example, OSHA has a permissible exposure limit (PEL) for trichloroethylene, or TCE, but it is already 20 years old.[12] Additionally, even OSHA admits that many of its PELs are outdated and do not adequately protect workers from chemicals.[13] As such, action taken by OSHA should not be a basis for excluding occupational uses from a risk evaluation scope.

Likewise, several TSCA-regulated chemicals also have FDA-regulated uses. Although methylene chloride is primarily used as a paint stripper and remover,[14] FDA has also approved it as a food additive for uses including as a solvent in the extraction of caffeine from green coffee beans.[15] A person who uses a methylene chloride-based paint stripper may also drink decaffeinated coffee and could be exposed from both sources. 1,4-Dioxane, used industrially as a solvent and chemical stabilizer, is a well-known contaminant in personal care and other consumer products. A recent analysis by EWG found that as many as 8,000 personal care products contain ethoxylated ingredients manufactured through a process that may create 1,4-dioxane as a byproduct.[16] An individual exposed to 1,4-dioxane in an occupational setting would likely also be exposed to 1,4-dioxane through their personal care or cleaning products.

Finally, non-TSCA uses include uses regulated by EPA, but under other statutes. Several of the first 10 chemicals—including 1,4-dioxane, TCE, tetrachlorethylene (perc), methylene chloride, asbestos, and carbon tetrachloride—are known to contaminate drinking water systems, according to nationwide water testing results analyzed in EWG's recently released Tap Water Database.[17] These chemicals are detected in concentrations that exceed health guidelines in drinking water served to millions of Americans, sometimes in combination with each other due to a common industrial source. Of these contaminants, EPA has yet to set an enforceable drinking water standard for 1,4-dioxane. The Maximum Contaminant Levels set for carbon tetrachloride, TCE, tetrachlorethylene, and methylene chloride are all less health-protective than other standards or public health goals promulgated by EPA or other public health agencies such as the California Office of Environmental Health Hazard Assessment. Even so, EWG's analysis found drinking water violations in some drinking water systems that had levels of carbon tetrachloride, TCE,

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[11] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).

[12] Envtl. Protection Agency, Scope of the Risk Evaluation for Trichloroethylene, p. 32 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf

[13] U.S. Dep't of Labor, Occupational Safety and Health Administration, Permissible Exposure Limits—Annotated Tables, https://www.osha.gov/dsg/annotated-pels/ (last accessed Sept. 19, 2017).

[14] ATSDR, Toxicological Profile for Methylene Chloride, pp. 1-2, https://www.atsdr.cdc.gov/toxprofiles/tp14.pdf (last accessed March 7, 2017).

[15] 21 C.F.R. § 173.255(c).

[16] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

[17] Envtl. Working Grp., EWG's Tap Water Database, All Contaminants, https://www.ewg.org/tapwater/chemical-contaminants.php#.WcCifNN96CQ.

and tetrachlorethylene exceeding the MCLs. Because water contamination is so pervasive, and EPA's enforceable drinking water standards are often not sufficiently protective, EPA should always consider exposure from drinking water as part of its risk assessments.

These examples show that people are exposed to chemicals in myriad ways that often fall under the jurisdiction of different laws and different agencies. While EPA would only regulate some of those uses under TSCA, uses and exposures that occur outside of TSCA's jurisdiction contribute to an individual's aggregate exposure, and thus could contribute to an unreasonable risk of injury to health and must be considered.

Must be based on adequate information

EPA should not omit a condition of use from the scope of the risk assessment because data on that particular use is lacking. For example, EPA has insufficient information about the likely exposure of workers and people living in homes that use HBCD insulation. EPA also has limited information about 1,4-dioxane levels in products that contain ethoxylated ingredients. EPA should study exposures rather than make assumptions based on the limited data. After all, the law requires EPA to actively seek "reasonably available information" about conditions of use from stakeholders.[18]

"Reasonably available" is defined broadly in the final risk evaluation rule to include not only information EPA possesses, but also all information EPA can "reasonably generate, obtain, and synthesize for use in risk evaluations."[19] This would include information published in scientific journals and industry studies. It would also include information already collected by state governments or under foreign regulations like the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) in Europe. If EPA knows this information exists and was submitted to other governments, it should take measures to request the same information from the manufacturers or processors responsible for its submission. Additionally, EWG encourages EPA to rely on the appropriate use of defaults, or calculated uncertainty factors when specific information is missing. Finally, EPA has various tools under sections 4, 8(a), 8(c), 11 and 26(a) to order testing or solicit information as needed to fill data gaps.

Exposure from contaminants or impurities

EWG is concerned by EPA's stated intent to generally exclude impurities and other "de minimis" exposures from the scope of its risk evaluations.[20]

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[18] 15 U.S.C. § 2625(k) ("The Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator."); 15 § 2605(b)(4)(F)(i).

[19] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33748 (July 20, 2017) (to be codified at 40 C.F.R. pt. 702.33).

[20] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017)("EPA may choose not to include a particular impurity within the Scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the impurity would be 'de minimis' or otherwise insignificant.")

This general exclusion falsely equates de minimis exposures with low risk. It disregards the significant body of evidence that hormone disruptors and developmental toxicants may cause adverse effects at very low doses, and ignores the possibility of nonmonotonic dose-response curves. The pharmaceutical literature is rife with examples of nonmonotonicity, timing and age-group specific toxicity concerns.[21] Furthermore, even de minimis exposures contribute to an individual's aggregate exposure to a chemical.

An important example is 1,4-dioxane. 1,4-Dioxane is a well-known impurity that occurs as a byproduct of the ethoxylation process. In the scoping document for 1,4-dioxane, EPA has indicated it will exclude these uses from the scope of its evaluation. Specifically, EPA states that:

> In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane.[22]

This approach is backwards. 1,4-Dioxane is a likely carcinogen and is associated with several other health effects, including liver and kidney damage, lung irritation, and eye, nose, and throat irritation.[23] Whether the presence of 1,4-dioxane in a product is intentional or the result of contamination does not change the potential health risks. Furthermore, it makes more sense to examine the risks from 1,4-dioxane formation in the context of the risk evaluation on 1,4-dioxane when EPA will be looking at other routes of 1,4-dioxane exposure and specifically analyzing the risks from 1,4-dioxane.

Several chemicals form 1,4-dioxane as part of the ethoxylation process. An analysis of EWG's Skin Deep database found that as many as 8,000 products contained ethoxylated ingredients that create 1,4-dioxane as a byproduct during manufacturing.[24] Presumably, future EPA risk evaluations on any of those ethoxylated chemicals will be focused on the risks posed by those chemicals themselves, with 1,4-dioxane formation considered only as a secondary issue. Furthermore, evaluating 1,4-dioxane formation as part of the risk evaluation for each ethoxylated chemical separately—each of which could be years or decades apart—would give EPA a disjointed and incomplete picture of the real problem.

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[21] See, e.g., Non-monotonic Dose Response Curves, Our Stolen Future, http://www.ourstolenfuture.org/NewScience/lowdose/nonmonotonic.htm (last visited Sept. 19, 2017).
[22] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 8 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf (emphasis added).
[23] ATSDR, Toxicological Profile for 1,4-dioxane, Relevance to Public Health, p. 2, https://www.atsdr.cdc.gov/toxprofiles/tp187-c2.pdf (last accessed Sept. 19, 2017).
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As EPA admits,[25] there is little information about how widespread contamination from 1,4-dioxane is in consumer products with ethoxylated ingredients. Because it's not intentionally added it does not need to be listed on product labels, and companies are not required to measure or disclose levels of 1,4-dioxane in their products. As such, there is little way to know if 1,4-dioxane is present and, if so, at what levels. While manufacturers can take steps to minimize 1,4-dioxane formation or vacuum strip it from products, manufacturers are also not required to report if they are doing so.[26] EPA should not make assumptions based on what it does not know, but should instead study the issue.

Without more information, EPA cannot assume that 1,4-dioxane exposures through personal care and other consumer products are minimal and not a concern. Americans use several different kinds of personal care products every day, many of which contain ethoxylated ingredients and could be contaminated with 1,4-dioxane. It is reasonable to assume that many people exposed through their personal care products might also be exposed to 1,4-dioxane residues through cleaners, paints, dyes, or other consumer products. Those same individuals may also be exposed to 1,4-dioxane through drinking water, or may live in a community close to where 1,4-dioxane is processed, manufactured or disposed of. As such, even those "de minimis" exposures from 1,4-dioxane contamination can add up and contribute to an individual's aggregate exposure. Thus, these exposures should be included in the scope of risk evaluations so that EPA can more accurately gauge overall exposure and control risks.

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When EPA identifies "any potentially exposed or susceptible subpopulations" and "the hazards to health and the environment that EPA plans to evaluate," the agency should conduct outreach to communities likely to be home to potentially exposed or susceptible subpopulations. These communities may possess crucial information about hazards that the agency may itself lack. For

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[25] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 21 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf ("The extent that manufacturers or processors apply controls or processes to minimize or remove 1,4-dioxane in surfactants during manufacture or before formulation in consumer products is unknown and likely varies by sector.")

[26] *Id.*("manufacturers can apply controls to minimize the formation of 1,4-dioxane or remove most of the 1,4-dioxane present in these products through a vacuum stripping process").

[27] Envtl. Protection Agency, EJ 2020 Action Agenda: EPA's Environmental Justice Strategy, https://www.epa.gov/environmentaljustice/ej-2020-action-agenda-epas-environmental-justice-strategy (last visited Sept. 19, 2017).

example, as highlighted in the comments submitted by Earthjustice et al. in March,[28] such communities are in the best position to inform EPA about nursing homes or schools located near sites that increase the likelihood of their exposures to the chemical. Additionally, workers may be best able to identify real-world occupational exposures to chemicals, including roles and responsibilities that create highly exposed subgroups within their ranks. Other federal, state, and local regulatory authorities may also possess information necessary to establishing the proper scope of a risk assessment. For example, the California EPA has developed child-specific risk values for certain chemicals like atrazine and chlorpyrifos. Those values compare children's susceptibility to adults' by specifically examining child-specific routes of exposure.[29] EPA should review California EPA's approach and adopt its risk values as appropriate, and incorporate information from the analysis California EPA has already completed.

Aggregate and cumulative exposures

As part of a risk assessment, EPA is required to describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered.[30] As emphasized in the above sections, EWG strongly believes that considering the *aggregate* exposures will provide a more robust analysis of the total risk a chemical poses, and that EPA's scoping documents should reflect consideration of those aggregate exposures.

To properly assess aggregate exposures, EPA must consider exposures throughout the lifecycle of the chemical from all routes and pathways, including exposures from conditions of use not regulated by TSCA. This includes exposures from food, drinking water, pesticides, and personal care products, even if those uses are not specifically regulated during section 6(a) rulemaking. EWG emphasizes that this approach should include aggregate exposures from trace contaminants, such as asbestos fibers sometimes found in talc products,[31] or 1,4-dioxane in cleaning and personal care products that contain ethoxylated ingredients.[32]

When possible, EPA should also consider cumulative exposures when scoping a risk evaluation. EPA has explicit authority to order testing and prescribe protocols and methodologies for a number of health and environmental effects – including "cumulative or synergistic effects."[33] Considering cumulative exposures is in line with EPA's priorities and consistent with the best practices for risk evaluations. In *Framework for Cumulative Risk Assessment* (2003), EPA states,

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[28] Alaska Community Action on Toxics, et al., Comments on Scope of the Risk Evaluations for the First Ten Chemicals Under the Toxic Substances Control Act (Mar. 15, 2017).
[29] Cal. EPA, Office of Envtl. Health Hazard Assessment, Child-Specific Reference Doses Finalized to Date, http://oehha.ca.gov/risk-assessment/chrd/table-all-chrds (Jun. 22, 2010).
[30] 15 U.S.C. § 2605(b)(4)(F)(ii).
[31] Ronald Gordon, et. al., Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women, 20 Int'l J. of Occupational and Envt'l Health 318 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164883.
[32] Agency for Toxic Substances & Disease Registry, Public Health Statement for 1,4-Dioxane, Toxic Substances Portal (April 2012), https://www.atsdr.cdc.gov/phs/phs.asp?id=953&tid=199.
[33] 15 U.S.C. § 2603(b)(2)(A).

"Assessing cumulative risk through complex exposures is one of the Agency's high priorities…and it is germane and of great interest to all program and regional offices."[34]

Considering cumulative exposures is important because people and vulnerable subpopulations can be exposed to multiple chemicals and stressors that contribute to the same adverse health effects. The National Academy of Sciences (NAS) has noted the need to evaluate the cumulative effects of phthalates and also pointed to the fact that lead and mercury can collectively affect brain development.[35] Additionally, cumulative exposures to multiple carcinogenic solvents (TCE, 1,4-dioxane, methylene chloride and perchloroethylene) via air and drinking water may pose unique risks for people living near sites with industrial contamination. Taking such cumulative impacts into consideration would improve current assessments, and to the extent possible should be included in scoping.

EPA may consider collective exposure to groups of similar chemicals, and use the Adverse Outcome Pathway framework and database[36] to identify where cumulative effects may be an issue. EPA should follow the cumulative risk assessment process recommended by the National Academy of Sciences (NAS) in their Phthalates and Cumulative Risk Report.[37] When specific information is not available, EPA may use default values to account for cumulative exposures.

Conclusion

EWG appreciates the opportunity to comment on the scoping documents for the first 10 TSCA substances. We hope that these comments will help EPA to reevaluate the scoping documents of the first 10 TSCA substances so that they address fully the ways in which vulnerable and chemically over-burdened populations around the country are placed at risk by these chemicals. We look forward to continuing to participate in EPA's risk evaluation and risk management efforts under TSCA. Should you have any additional questions, please feel free to reach out to Melanie Benesh, Legislative Attorney at EWG, 202-939-0120, mbenesh@ewg.org.

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[34] Envtl. Protection Agency, Framework for Cumulative Risk Assessment, p. xi https://www.epa.gov/sites/production/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (last accessed Sept. 19, 2017).

[35] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508.

[36] Adverse Outcome Pathway Knowledge Database, Org. for Econ. Co-Operation & Dev., http://aopkb.org/ (last visited March 20, 2016).

[37] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508..

HSIA
halogenated solvents industry alliance, inc.

September 19, 2017

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: Trichloroethylene [EPA-HQ-OPPT-2016-0737]
Tetrachloroethylene [EPA-HQ-OPPT-2016-0732]
Methylene Chloride [EPA-HQ-OPPT-2016-0742]
Carbon Tetrachloride [EPA-HQ-OPPT-2016-0733]

Dear Sirs:

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) amended the Toxic Substances Control Act (TSCA) and established several regulatory timelines. Under TSCA § 6(b)(4)(D), EPA released scoping documents for the first ten chemicals targeted for evaluation under LCSA, including the chlorinated solvents trichloroethylene (TCE), tetrachloroethylene (perchloroethylene or PCE), and methylene chloride (dichloromethane or DCM). The general comments included in this submission are also applicable to the scoping document for carbon tetrachloride (CTC).

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers, distributors and users of chlorinated solvents. HSIA appreciates the opportunity to comment on problem formulation for the above-referenced scoping documents, as solicited in the notice announcing their release. 82 Fed. Reg. 31592 (July 7, 2017). In that notice, EPA acknowledged that the initial scoping documents did not achieve the quality anticipated for future scoping documents:

> "The first 10 chemical substances were not subject to prioritization, the process through which EPA expects to collect and screen much of the relevant information about chemical substances that will be subject to the risk evaluation process. As a result, EPA had limited ability to process all the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. Hence, the scope documents for the first 10 chemicals are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on drafts of these scope documents, as it intends to do for future scope documents."

One of the challenges for EPA in developing the required scoping documents was doing so prior to release of the final *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (Risk Evaluation Rule)*, 82 Fed. Reg. 33726 (July 20, 2017). Due to the acknowledged limitations of the initial scoping documents, EPA announced that it would:

> "publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals."

Typically, as will be discussed below, EPA treats Planning and Scoping and Problem Formulation as separate, albeit iterative, activities. The above statement indicates that EPA clearly has concerns with the quality of the Planning and Scoping element released in June and hopes to address those concerns through creation of a Problem Formulation document. Both elements are important in designing a credible risk assessment (or risk evaluation under LCSA). Recognizing that aspect, HSIA is pleased to submit the following comments for consideration by EPA in its development of the problem formulation documents for the four chlorinated organics (TCE, PCE, DCM, and CTC) found on the initial list of 10 chemicals under consideration.

General Recommendation

HSIA would strongly recommend that, in development of the problem formulation documents for the four chlorinated organics, EPA give serious consideration to its own guidance document *Framework for Human Health Risk Assessment to Inform Decision Making*. Although briefly mentioned in the Risk Evaluation Rule, there is no mention of the document in the June scoping documents for the four chlorinated compounds. We find this surprising, as application of the framework would appear to address many of the limitations acknowledged by EPA. As summarized in the 2014 document:

> "[t]he Framework for Human Health Risk Assessment to Inform Decision Making lays out a Framework for conducting human health risk assessments in support of decision making at EPA. It focuses on the planning and scoping and problem formulation steps, drawing on NRC (2009) and other advisory groups, and EPA experience. For example, the Framework addresses recommendations in the Silver Book (NRC 2009) on assuring the utility of risk assessment, which the Framework terms as being fit for purpose. . . [T]he NRC's 1983 four-step risk assessment paradigm is maintained, but there is increased emphasis on interaction between risk assessors and risk managers in planning the assessment to maximize utility. Emphasis on utility is maintained throughout the process, beginning with planning and scoping and continuing through the evaluation of the applicability of the risk assessment in informing decisions."

and

> "[a]pplication of the Framework, with its emphasis on problem formulation and the utility of the risk assessment, ultimately will result in better, more transparent choices among risk management options. This Framework builds on Agency guidelines, policies and guidance and is directed at improving risk assessment products but does not overturn or in any way change existing science policy decisions."

Specific Recommendations

Although the four chlorinated organics from the initial list of ten chemicals under consideration were not subjected to the LCSA prioritization process anticipated for chemicals considered in the future, it must be noted that all have been in commerce for decades and all should be considered "data-rich." As such, they all have a history of already being heavily regulated/controlled under a variety of existing federal and state programs. This makes them somewhat unique, particularly when compared against chemicals newly introduced into commerce, and raises some interesting problems in evaluating them under LCSA.

As mentioned earlier, the initial scoping documents for the four chlorinated organics were released prior to issuance of the Risk Evaluation Rule. In the preamble to that rule, which became effective on

September 18, EPA provided clarification on several issues that were problematic/unclear in the draft version released under the previous administration. In the following sections, HSIA addresses several of these specific issues in hopes that EPA will consider them during development of the problem formulation documents.

EPA's interpretation of its regulatory mandate under LCSA

In the Risk Evaluation Rule, EPA's clarified its regulatory mandate under LCSA:

> "EPA interprets the mandates under section 6(a)–(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur. . . ."

HSIA agrees with this position. As will be seen in several of the following recommendations, further broadening of that mandate for chemicals that are already subjected to extensive regulation presents serious conflicts both in assessing potential human health and environmental risks and in any subsequent risk management decisions. The focus should be restricted to chemicals in commerce from this point forward.

EPA should use discretion in its selection of conditions of use

One of the most contentious issues associated with the evaluation of risk under LCSA is "conditions of use." The issue focuses on the question "should any/all actual/potential uses of a chemical in the past/present/future be considered in the risk evaluation?" LCSA does not require the Agency to conduct full risk evaluations based on all conditions of use and nowhere in the law is "conditions of use" preceded by "all." Expansion of the term "conditions of use" beyond the intent of Congress may distract from and negatively impact EPA's ability to conduct meaningful risk evaluations in a timely manner.

EPA should exclude certain *de minimis* conditions of use

The four chlorinated organics included on the initial list are all used as intermediates in the synthesis of other chemicals. These are the largest uses of CTC and TCE. Such feedstock use takes place within closed systems in restricted-access facilities where workers are operating under Occupational Safety & Health Administration (OSHA) regulations with appropriate personal protective equipment (PPE). Given the nature of the chlorinated organics, a leak detection and repair (LDAR) program is typically in place and fugitive emissions are monitored. The only potential human exposure would be to on-site workers, whose risks are managed under a facility's health and safety program, which falls under the jurisdiction of OSHA. Potential off-site exposures would only occur at or beyond the facility fence-line, and air modeling of fugitive emissions typically shows maximum air concentrations occurring very close to the release point (*i.e.*, within the facility). In the preamble to the Risk Evaluation Rule, EPA addresses the issue of *de minimis* exposures such as these with the following rather ambiguous language:

> "EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only '*de minimis*' exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate."

Given our understanding of the use of these solvents as intermediates, HSIA believes there is a sufficient basis to exclude this "condition of use" from further consideration in the risk evaluation.

EPA should consider a tiered approach to address *de minimis* and/or heavily regulated exposures

For those situations where EPA is not comfortable excluding certain "conditions of use" based on anticipated *de minimis* exposures, HSIA recommends that the Agency consider a tiered approach for screening potential risks as an initial step in the risk evaluation. Although our preference would certainly be to exclude those *de minimis* and/or heavily regulated "conditions of use" during the scoping/problem formulation stage, we support EPA's recognition in the Risk Evaluation Rule that in order to efficiently carry out the LCSA Congressional mandate, EPA must maintain the flexibility to issue a decision on specific "conditions of use" in a tiered, staged approach.

Legacy sources of exposure should not be addressed under LCSA

HSIA recommends that legacy sources of exposure should be excluded from the risk evaluation process under LCSA. Legacy sources of exposure typically refer to historical releases of a chemical to the environment associated with misuse or disposal. Although legacy environmental sources of exposure certainly exist for the four chlorinated organics, they have been effectively managed for decades under various federal programs (*i.e.*, CERCLA, RCRA, CAA, etc.). Many states also have stringent programs for addressing legacy contamination from these chemicals. Management of legacy contamination through the various federal and state programs is already risk-based and adding an additional risk-management program to the existing mix would be duplicative and not needed. The following statement from the preamble to the Risk Evaluation Rule indicates that EPA feels it could "exercise its discretion" on decisions relating to exclusion of a particular condition of use.

> "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks."

From a practical perspective, it is difficult to conceive how risks from a legacy source of exposure would even be managed under LCSA. For the four chlorinated organics, once a legacy exposure source (*i.e.*, existing environmental contamination) is discovered, responsibility for management of any human health or environmental risk would be assumed by the state. If the source was sufficiently large and generated a sufficiently high Hazard Ranking Score (HRS), it could be classified as a Superfund site under CERCLA.

Protection from workplace exposures to chemicals is the primary responsibility of OSHA, not EPA

As noted above, EPA has exclusionary discretion for "a condition of use [*i.e.*, exposure] that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks." As originally enacted and as updated by LCSA, TSCA requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."[1] It has been clear since passage of the Occupational Safety and Health Act in 1970 that workplace protection is the primary responsibility of OSHA.

The LCSA eliminated the requirement in TSCA § 6(a) that EPA protect "against [unreasonable] risk using the least burdensome requirements," but did not materially change the existing framework that

[1] TSCA § 9(d).

requires unreasonable risks to be addressed under statutory authority other than TSCA wherever possible. EPA's longstanding interpretation of this framework is as follows:

> "Under section 9(a)(1) of TSCA, the Administrator is required to submit a report to another Federal agency when two determinations are made. The first determination is that the Administrator has reasonable basis to conclude that a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. The second determination is that the unreasonable risk may be prevented or reduced to a sufficient extent by action taken by another Federal agency under a Federal law not administered by EPA. Section 9(a)(1) provides that where the Administrator makes these two determinations, EPA must provide an opportunity to the other Federal agency to assess the risk described in the report, to interpret its own statutory authorities, and to initiate an action under the Federal laws that it administers.
>
> "Accordingly, section 9(a)(1) requires a report requesting the other agency: (1) To determine if the risk may be prevented or reduced to a sufficient extent by action taken under its authority, and (2) if so, to issue an order declaring whether or not the activities described in the report present the risk described in the report.
>
> "Under section 9(a)(2), EPA is prohibited from taking any action under section 6 or 7 with respect to the risk reported to another Federal agency pending a response to the report from the ether Federal agency. There would be no similar restriction on EPA for any risks associated with a chemical substance or mixture that is not within the section 9(a)(1) determinations and therefore not part of the report submitted by EPA to the other Federal agency."[2]

It was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. When TSCA was enacted in 1976, Representative James Broyhill of North Carolina indicated that "it was the intent of the conferees that the Toxic Substance [Control] Act not be used, when another Act is sufficient to regulate a particular risk."[3] TSCA § 9(a) is substantively unchanged by the LCSA. The House Energy and Commerce Committee Report states: "H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals," and further clarifies that "while § 5 makes no amendment to TSCA § 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety."[4]

EPA applied this statutory directive in determining that the risk from 4,4' methylenedianiline (MDA) could be prevented or reduced to a significant extent under the OSH Act, and referring the matter for action by OSHA.[5] And in an analysis of TSCA § 9, EPA's Acting General Counsel concluded that

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[2] 4,4'-Methylenedianiline; Decision to Report to the Occupational Safety and Health Administration, 50 Fed. Reg. 27674 (July 5, 1985). EPA also has acted under § 9(a) to refer 1,3-butadiene and glycol ethers to OSHA, 50 Fed. Reg. 41393 (Oct. 10, 1985) and 51 Fed. Reg. 18488 (May 20, 1986), respectively, and to refer dioxins in bleached wood pulp and paper products to the Food and Drug Administration, 55 Fed. Reg. 53047 (Dec. 26, 1990).

[3] 122 Cong. Rec. H11344 (Sept. 28, 1976)

[4] H. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28.

[5] 50 Fed. Reg. 27674 (July 5, 1985).

"Congress expected EPA – particularly where the Occupational Safety and Health Act was concerned – to err on the side of making referrals rather than withholding them."[6]

If EPA were to identify a category of exposure deemed to present a risk that is unreasonable, these considerations indicate that referral under § 9(a) would be the appropriate course.[7] It is clear from Section 9(a) that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks.

EPA codified this principle in the Risk Evaluation Rule, 40 C.F.R. §702.39. EPA should adopt the OSHA permissible exposure limits (PELs) as the appropriate screening levels for potential risks to workers. If the 90th percentile estimates from the 8-hour time-weighted average (TWA) exposure concentrations are at or below the OSHA PELs, EPA should conclude a condition of no significant risk for worker exposures. However, it is possible that EPA could, if scientifically appropriate, decide to apply more recent American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) to evaluate potential risks to workers.

Occupational exposure limits, such as OSHA PELs and ACGIH TLVs, are derived to be protective for occupational exposures. The values are typically based on occupational epidemiology studies and, therefore, are especially relevant for worker populations. For example, occupational studies by their very nature include consideration of the healthy worker effect.[8] Occupational exposure limits also consider other factors unique to the workplace, such as technical feasibility. In general, occupational exposure limits should be considered protective for worker exposures. Such limits and their bases should be part of worker risk evaluations under the new TSCA.

Risk evaluations conducted under LCSA should be state-of-the-art

There have been significant developments in the science of risk assessment and in our understanding of mode of action for cancer and other apical endpoints in recent years. HSIA is encouraged that EPA has acknowledged these developments in the Risk Evaluation Rule and appears committed to including them in risk evaluations conducted under LCSA. Many of these developments are the result of concerns with EPA's IRIS program. HSIA believes that the following are necessary components of a state-of-the-art risk evaluation and should be part of the problem formulation documents.

Systematic Review: Although several of the chemicals from the initial list of ten to be evaluated under the amended TSCA are relatively data-rich, it is essential that a systematic review be undertaken to ensure that all existing hazard data are considered. The IRIS evaluation of TCE, for example, was completed in 2011 and an examination of that document reveals that many of the studies referenced are now more than a decade old. Although EPA indicated that many of the principles of systematic review were considered

[6] Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2.

[7] As noted above, TSCA § 9(a) provides that if the Administrator has reasonable basis to conclude that an unreasonable risk of injury is presented, and he determines, in his discretion, that the risk may be prevented or sufficiently reduced by action under another federal statute not administered by EPA, then the Administrator shall submit a report to that agency describing the risk. In the report, the Administrator shall request that the agency determine if the risk can be prevented or sufficiently reduced by action under the law administered by that agency; if so, the other agency is to issue an order declaring whether the risk described in the Administrator's report is presented, and is to respond to the Administrator regarding its prevention or reduction. The Administrator may set a time (of not less than 90 days) within which the response is to be made. The other agency must publish its response in the Federal Register. If the other agency decides that the risk described is not presented, or within 90 days of publication in the Federal Register initiates action to protect against the risk, EPA may not take any action under § 6 of TSCA.

[8] A healthy worker effect is based on observations in occupational epidemiology studies that workers usually exhibit lower overall death rates than the general population because the severely ill and chronically disabled are ordinarily excluded from employment (Li *et al.* 1999).

during the TCE IRIS evaluation, there have been significant developments in that process over the past decade. At the very least, the systematic review should consider all existing hazard data and, consistent with current approaches, publish acceptance criteria, including criteria to assess study quality, which are then used in the selection of key studies.

HSIA would recommend that a similar approach be applied to exposure data used for the risk evaluation. For example, a systematic review of air monitoring data should exclude data generated prior to the effective date of a National Emission Standard for Hazardous Air Pollutants which limited the emissions of a particular chemical from covered sources. Although EPA provides a fairly lengthy discussion on systematic review in the preamble to the Risk Evaluation Rule, it did not codify a definition for systematic review. Many of the elements of systematic review do, however, appear in the codified definition of "weight of scientific evidence" provided below.

Consideration of Best Available Science: HSIA strongly endorses the use of best available science in risk evaluations conducted under LCSA. Although Section 702.33 of the Risk Evaluation Rule provides a detailed definition of "best available science," the overarching principal is science that is reliable and unbiased. Several of the chlorinated solvents have suffered from EPA's reliance on scientific studies that were considered substandard by the scientific community. HSIA is hopeful that EPA's commitment to consideration of best available science, when combined with a formal systematic review process, will yield risk evaluations that are reliable.

Consideration of New Data: HSIA supports EPA's position on the acceptance of new data for consideration in the risk evaluation.

> "EPA does not intend to preclude the generation of new scientific information to inform risk evaluations, however, as mentioned in the discussion of reasonably available information, the extent to which EPA will consider any newly generated information in a risk evaluation will depend on the statutory deadlines."

Application of Weight of Scientific Evidence Approach: As discussed above, Section 702.33 of the Risk Evaluation Rule defines "weight of scientific evidence" as:

> ". . . a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."

Similar language regarding the "weight of scientific evidence" was included in the scoping documents for TCE , PCE , DCM and CTC released in June 2017 [excerpt from the TCE scoping document follows]:

> "EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent."

Whether or not a definition for systematic review is codified in the Risk Evaluation Rule is less important than EPA's commitment to integrate the process into risk evaluations conducted under LCSA. HSIA strongly supports that commitment for both hazard and exposure data.

Peer Review: Although the proposed Risk Evaluation Rule only provided lip-service to the concept of peer review, HSIA strongly supports EPA's commitment to the peer review process as described in the preamble to the final rule:

> "In addition to any targeted peer review of specific aspects of the analysis, the entire risk assessment will also undergo peer review [emphasis added], as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination. "

EPA's commitment to the peer review process under TSCA has, to date, been uneven. Although the TSCA Work Plan Chemicals Assessment for TCE, conducted in 2012, was subjected to external peer review, the final document contained an exposure scenario (*i.e.*, condition of use) that was not even included in the draft. Despite lack of peer review for that condition of use, EPA used the results of the risk assessment as the basis for a proposed ban.

Public Comment Period: LCSA requires that EPA allow for no less than a 30-day public comment period on a draft risk evaluation, prior to publishing a final risk evaluation. HSIA recommends that EPA allow at a minimum a 60-day public comment period following release of the draft problem formulation documents given their obvious importance in setting precedent for the program moving forward. Indeed, a public meeting to review and discuss public comments on the draft problem formulation documents could greatly facilitate agreement on the final product (*i.e.*, the risk evaluation).

Clearly, the scenarios examined in the 2014 TSCA Work Plan Chemicals Assessments should be re-evaluated. Language in the scoping documents for TCE and DCM, released by EPA in June 2017, indicates that conditions of use previously evaluated in 2014 TSCA Work Plan Chemical Risk Assessments may not be re-evaluated under the Risk Evaluation Rule. HSIA urges EPA to reconsider this position as part of problem formulation, for several reasons. First, as already mentioned, between publication of the peer-reviewed draft assessment for TCE in 2012 and release of the final version in 2014, EPA introduced a new "condition of use" (*i.e.*, spot cleaning) which was not subjected to peer review. Second, the Risk Evaluation Rule, which promulgated the procedure(s) to be followed in conducting a risk evaluation to satisfy requirements under LCSA, was not published until July 20, 2017, three years after finalization of the Work Plan Chemical Assessments for TCE and MC. All significant "conditions of use" should be evaluated in compliance with the Risk Evaluation Rule, which requires significant aspects not addressed or applied in the previous risk assessments, such as consideration of best available science and application of a weight of the scientific evidence approach.

To facilitate EPA's review of these uses, HSIA is submitting comments on the earlier proposed rules (and related risk assessments) to the relevant dockets.

EPA's approach for evaluating environmental impacts under LCSA is problematic

Under LCSA, EPA is required to evaluate potential chemical impacts on the environment and HSIA has serious concerns about the approach described in the final Risk Evaluation Rule. The scoping documents for the four chlorinated organics state that:

> ". . . manufacturing, processing, use and disposal . . . . . can result in releases to air, water, sediment and soil. EPA expects to consider exposures to the environment and ecological receptors that occur via these exposure pathways or media . . . . . in conducting the risk evaluation . . . ."

The Risk Evaluation Rule appears to expand the potential scope for the evaluation of environmental impacts even further. Under §702.43(4) (*i.e.*, Considerations for environmental risk evaluations), the rule states:

> "For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance."

In addition to being concerned about the level of effort required to carry out such an activity, HSIA is concerned that such an evaluation would have to be location-specific. If, for example, EPA is interested in evaluating potential environmental impacts from a manufacturing facility, those impacts will have to be based on either measured or modeled media concentrations. The fate and transport of chemicals into air, soil, sediment, and surface water is known to be influenced by factors that are location- and site-specific and any adverse impacts will be applicable to that specific facility only. The air modeling of emitted chemicals from a manufacturing facility into environmental media surrounding that facility, for example, will be influenced by many factors, including local meteorology, terrain, proximity to surface water bodies, and distance to the facility boundaries, among others.

As described, the evaluation of environmental impacts under LCSA could result in a situation where a "condition of use" is found to be associated with unacceptable environmental impacts, yet the "condition of use" would only be relevant at a specific facility. That same "condition of use" could be acceptable at another facility operating under the exact same conditions, creating a real risk management dilemma.

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HSIA appreciates the opportunity to provide these comments on this important step of problem formulation.

Respectfully submitted,

Faye Graul

Faye Graul,
Executive Director

September 19, 2017

EWG Comments on the Risk Evaluation Scoping for the First 10 Chemicals Under TSCA

Docket ID Nos.: EPA-HQ-OPPT-2016-0723 (1,4- Dioxane); EPA-HQ-OPPT-2016-0725 (Pigment Violent 29) EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene (also known as perchloroethylene)); EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride); EPA-HQ-OPPT-2016-0735 (Cyclic Aliphatic Bromide Cluster (HBCD)); EPA-HQ-OPPT-2016-0736 (Asbestos); EPA-HQ-OPPT-2016-0737 (Trichloroethylene (TCE)); EPA-HQ-OPPT-2016-0741 (1-Bromopropane); EPA-HQ-OPPT-2016-0742 (Methylene Chloride); and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone (NMP)).

The Environmental Working Group (EWG) is a nonprofit advocacy organization dedicated to improving environmental health. EWG has long advocated for stronger federal chemical regulations and spent over a decade advocating for reforms to strengthen the Toxic Substances Control Act (TSCA). The Frank R. Lautenberg Chemical Safety for the 21st Century Act (hereinafter "Lautenberg Act") for the first time will require the Environmental Protection Agency (EPA) to comprehensively review existing chemicals on the TSCA inventory—starting with 10 work plan chemicals, as required by section 6(b)(2)(A).[1] As the first chemicals assessed under the recently overhauled law, these first 10 assessments represent an early test of the strength of the new law. As such, it is important that the scopes of these first 10 chemical risk evaluations adequately consider the diverse uses of each chemical and the unique ways that vulnerable and chemically over-burdened populations may be at risk.

We submit these comments generally to apply to all 10 scoping documents released by EPA on June 22, 2017. The following comments are meant to assist EPA to strengthen the proposed scopes of the first 10 chemicals before it moves into the problem formulation phase of the risk evaluation process. In particular, EWG comments that EPA's scoping documents on the first 10 chemicals should be revised as needed to ensure they include:

- Reasonably foreseeable uses like accidents, misuses, and off-label uses
- The entire lifecycle of the chemical
- Exposures from non-TSCA uses
- Contaminants and low-concentration uses that contribute to overall exposure
- Exposures for which data is limited
- Risks to potentially exposed and susceptible populations
- Risks from aggregate and cumulative exposures

Accidents, misuses, and off-label uses

[1] 15 U.S.C. § 2605(b)(2)(A).

Pursuant to TSCA section 6(b)(4)(D), a chemical's scoping document should include "the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider."[2]

The Lautenberg Act defined "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[3] The plain language of this definition requires EPA to consider not only the intended and known uses of a chemical, but also any "reasonably foreseeable uses."

Reasonably foreseeable uses should include accidents like chemical spills and leaks that can contaminate air, water, and soil. The National Environmental Policy Act ("NEPA") highlights how "reasonable foreseeability" includes accidental releases in the context of environmental law. NEPA requires federal agencies to prepare an environmental impact statement ("EIS") for any proposed major federal action "significantly affecting the quality of the human environment."[4]

Other language in TSCA further underscores the intention to include accidental or inadvertent releases or exposures. The process for prioritizing chemicals requires EPA to consider "storage near significant sources of drinking water."[5] This is a clear reference to potential risks from accidental spills or leaks, or even criminal releases, into drinking water.

EWG is further concerned by EPA's stated intent to generally exclude "intentional misuses" from the scope of a chemical risk evaluation.[6] Reasonably foreseeable uses would also include foreseeable misuses, whether they are intentional or not. For example, a consumer may foreseeably misuse cleaning and other consumer products in several ways. A bathtub cleaner may also be used to clean the bathroom sink. A cleaner that is meant to be sprayed from 8 to 10 inches away may instead be sprayed from 3 inches away. Consumers and workers may apply more or less of a product than what is directed. Chemical facilities may intentionally improperly release or dispose of a chemical. These misuses are reasonably foreseeable and should be included in the scope of a risk evaluation.

Lifecycle of chemical, including legacy uses

Section 6(a) requires EPA to regulate when an unreasonable risk is posed by the "manufacture, processing, distribution in commerce, use, or disposal" of a chemical or "any combination such activities."[7] This makes clear that in the scope of a risk assessment, EPA must account for the entire lifecycle of the chemical, including risks during production, processing, distribution, recycling, and disposal, or any combination of those activities. It follows that the scope of EPA's risk evaluations should include both current and also legacy uses, as well as legacy disposal. As

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[2] 15 U.S.C. 2605 (b)(4)(D).
[3] 15 U.S.C. 2602(4).
[4] 42 U.S.C. § 4332(2)(C)(i).
[5] 15 U.S.C. § 2605(b)(1)(A).
[6] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).
[7] 15 U.S.C. 2605(a).

such, EWG is concerned by EPA's stated intention to focus on "uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal."[8]

This interpretation undermines the design of TSCA as a cradle-to-grave statute and is at odds with EPA's clear mandate to evaluate and regulate risks at the end of a chemical's lifecycle. Excluding legacy uses is also at odds with EPA's requirement to "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance."[9] To fully consider the frequency and number of exposures to a chemical, EPA must consider likely exposure from all sources—regardless of whether the exposure came from an ongoing or a legacy use.

Asbestos and the HBCD provide important examples. Both chemicals may be found in previously installed insulation and other building materials in homes, offices, schools and other buildings. They can be released if disturbed, creating an exposure risk. Thousands of American homes have asbestos-containing vermiculite insulation, and millions have HBCD-containing insulation board. As insulation ages, chemicals like HBCD and asbestos can migrate into household dust.

Building materials may also be improperly removed or disposed of, creating additional exposure risks. For example, in 2016, the Washington State Attorney General brought charges against a hotel owner for improper asbestos removal.[10] According to the news release, the owner lied about the extent of renovations in order to get around asbestos surveying and permit requirements. As a result, workers, inspectors, and people living near the hotel were all potentially exposed to unsafe levels of asbestos from legacy uses.

The prevalence of these legacy uses underscores the importance of including them in risk evaluations. Without considering exposure from legacy uses or disposal, EPA will be unable to assess the aggregate exposure because it will not have a complete picture of the "likely duration, intensity, frequency, and number of exposures to a chemical."

Consideration of non-TSCA uses

The requirement that EPA consider the "hazards, exposures, [and] conditions of use" in its scoping documents and also the "likely duration, intensity, frequency, and number of exposures" means that EPA must also consider uses covered by other agencies and statutes.

EWG is concerned by EPA's assertion that "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly

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[8] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017).
[9] 15 U.S.C. § 2605(b)(4)(F)(iv).
[10] Press Release, Washington State Office of the Attorney General, AG Files Criminal Charges Against Hotel Owner over Asbestos Removal (May 11, 2016), http://www.atg.wa.gov/news/news-releases/ag-files-criminal-charges-against-hotel-owner-over-asbestos-removal.

where the other agency has effectively managed the risks."[11] Even if another agency has taken steps to manage risk from a particular use, that doesn't mean the use does not contribute to exposure or that the risk has been eliminated. For example, many of the first 10 chemicals pose occupational risks that may be regulated by OSHA. However, oftentimes OSHA's regulations need to be updated or do not go far enough. For example, OSHA has a permissible exposure limit (PEL) for trichloroethylene, or TCE, but it is already 20 years old.[12] Additionally, even OSHA admits that many of its PELs are outdated and do not adequately protect workers from chemicals.[13] As such, action taken by OSHA should not be a basis for excluding occupational uses from a risk evaluation scope.

Likewise, several TSCA-regulated chemicals also have FDA-regulated uses. Although methylene chloride is primarily used as a paint stripper and remover,[14] FDA has also approved it as a food additive for uses including as a solvent in the extraction of caffeine from green coffee beans.[15] A person who uses a methylene chloride-based paint stripper may also drink decaffeinated coffee and could be exposed from both sources. 1,4-Dioxane, used industrially as a solvent and chemical stabilizer, is a well-known contaminant in personal care and other consumer products. A recent analysis by EWG found that as many as 8,000 personal care products contain ethoxylated ingredients manufactured through a process that may create 1,4-dioxane as a byproduct.[16] An individual exposed to 1,4-dioxane in an occupational setting would likely also be exposed to 1,4-dioxane through their personal care or cleaning products.

Finally, non-TSCA uses include uses regulated by EPA, but under other statutes. Several of the first 10 chemicals—including 1,4-dioxane, TCE, tetrachlorethylene (perc), methylene chloride, asbestos, and carbon tetrachloride—are known to contaminate drinking water systems, according to nationwide water testing results analyzed in EWG's recently released Tap Water Database.[17] These chemicals are detected in concentrations that exceed health guidelines in drinking water served to millions of Americans, sometimes in combination with each other due to a common industrial source. Of these contaminants, EPA has yet to set an enforceable drinking water standard for 1,4-dioxane. The Maximum Contaminant Levels set for carbon tetrachloride, TCE, tetrachlorethylene, and methylene chloride are all less health-protective than other standards or public health goals promulgated by EPA or other public health agencies such as the California Office of Environmental Health Hazard Assessment. Even so, EWG's analysis found drinking water violations in some drinking water systems that had levels of carbon tetrachloride, TCE,

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[11] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).

[12] Envtl. Protection Agency, Scope of the Risk Evaluation for Trichloroethylene, p. 32 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf

[13] U.S. Dep't of Labor, Occupational Safety and Health Administration, Permissible Exposure Limits—Annotated Tables, https://www.osha.gov/dsg/annotated-pels/ (last accessed Sept. 19, 2017).

[14] ATSDR, Toxicological Profile for Methylene Chloride, pp. 1-2, https://www.atsdr.cdc.gov/toxprofiles/tp14.pdf (last accessed March 7, 2017).

[15] 21 C.F.R. § 173.255(c).

[16] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

[17] Envtl. Working Grp., EWG's Tap Water Database, All Contaminants, https://www.ewg.org/tapwater/chemical-contaminants.php#.WcCifNN96CQ.

and tetrachlorethylene exceeding the MCLs. Because water contamination is so pervasive, and EPA's enforceable drinking water standards are often not sufficiently protective, EPA should always consider exposure from drinking water as part of its risk assessments.

These examples show that people are exposed to chemicals in myriad ways that often fall under the jurisdiction of different laws and different agencies. While EPA would only regulate some of those uses under TSCA, uses and exposures that occur outside of TSCA's jurisdiction contribute to an individual's aggregate exposure, and thus could contribute to an unreasonable risk of injury to health and must be considered.

Must be based on adequate information

EPA should not omit a condition of use from the scope of the risk assessment because data on that particular use is lacking. For example, EPA has insufficient information about the likely exposure of workers and people living in homes that use HBCD insulation. EPA also has limited information about 1,4-dioxane levels in products that contain ethoxylated ingredients. EPA should study exposures rather than make assumptions based on the limited data. After all, the law requires EPA to actively seek "reasonably available information" about conditions of use from stakeholders.[18]

"Reasonably available" is defined broadly in the final risk evaluation rule to include not only information EPA possesses, but also all information EPA can "reasonably generate, obtain, and synthesize for use in risk evaluations."[19] This would include information published in scientific journals and industry studies. It would also include information already collected by state governments or under foreign regulations like the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) in Europe. If EPA knows this information exists and was submitted to other governments, it should take measures to request the same information from the manufacturers or processors responsible for its submission. Additionally, EWG encourages EPA to rely on the appropriate use of defaults, or calculated uncertainty factors when specific information is missing. Finally, EPA has various tools under sections 4, 8(a), 8(c), 11 and 26(a) to order testing or solicit information as needed to fill data gaps.

Exposure from contaminants or impurities

EWG is concerned by EPA's stated intent to generally exclude impurities and other "de minimis" exposures from the scope of its risk evaluations.[20]

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[18] 15 U.S.C. § 2625(k) ("The Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator."); 15 § 2605(b)(4)(F)(i).

[19] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33748 (July 20, 2017) (to be codified at 40 C.F.R. pt. 702.33).

[20] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017)("EPA may choose not to include a particular impurity within the Scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the impurity would be 'de minimis' or otherwise insignificant.")

This general exclusion falsely equates de minimis exposures with low risk. It disregards the significant body of evidence that hormone disruptors and developmental toxicants may cause adverse effects at very low doses, and ignores the possibility of nonmonotonic dose-response curves. The pharmaceutical literature is rife with examples of nonmonotonicity, timing and age-group specific toxicity concerns.[21] Furthermore, even de minimis exposures contribute to an individual's aggregate exposure to a chemical.

An important example is 1,4-dioxane. 1,4-Dioxane is a well-known impurity that occurs as a byproduct of the ethoxylation process. In the scoping document for 1,4-dioxane, EPA has indicated it will exclude these uses from the scope of its evaluation. Specifically, EPA states that:

> In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane.[22]

This approach is backwards. 1,4-Dioxane is a likely carcinogen and is associated with several other health effects, including liver and kidney damage, lung irritation, and eye, nose, and throat irritation.[23] Whether the presence of 1,4-dioxane in a product is intentional or the result of contamination does not change the potential health risks. Furthermore, it makes more sense to examine the risks from 1,4-dioxane formation in the context of the risk evaluation on 1,4-dioxane when EPA will be looking at other routes of 1,4-dioxane exposure and specifically analyzing the risks from 1,4-dioxane.

Several chemicals form 1,4-dioxane as part of the ethoxylation process. An analysis of EWG's Skin Deep database found that as many as 8,000 products contained ethoxylated ingredients that create 1,4-dioxane as a byproduct during manufacturing.[24] Presumably, future EPA risk evaluations on any of those ethoxylated chemicals will be focused on the risks posed by those chemicals themselves, with 1,4-dioxane formation considered only as a secondary issue. Furthermore, evaluating 1,4-dioxane formation as part of the risk evaluation for each ethoxylated chemical separately—each of which could be years or decades apart—would give EPA a disjointed and incomplete picture of the real problem.

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[21] See, e.g., Non-monotonic Dose Response Curves, Our Stolen Future, http://www.ourstolenfuture.org/NewScience/lowdose/nonmonotonic.htm (last visited Sept. 19, 2017).
[22] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 8 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf (emphasis added).
[23] ATSDR, Toxicological Profile for 1,4-dioxane, Relevance to Public Health, p. 2, https://www.atsdr.cdc.gov/toxprofiles/tp187-c2.pdf (last accessed Sept. 19, 2017).
[24] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

As EPA admits,[25] there is little information about how widespread contamination from 1,4-dioxane is in consumer products with ethoxylated ingredients. Because it's not intentionally added it does not need to be listed on product labels, and companies are not required to measure or disclose levels of 1,4-dioxane in their products. As such, there is little way to know if 1,4-dioxane is present and, if so, at what levels. While manufacturers can take steps to minimize 1,4-dioxane formation or vacuum strip it from products, manufacturers are also not required to report if they are doing so.[26] EPA should not make assumptions based on what it does not know, but should instead study the issue.

Without more information, EPA cannot assume that 1,4-dioxane exposures through personal care and other consumer products are minimal and not a concern. Americans use several different kinds of personal care products every day, many of which contain ethoxylated ingredients and could be contaminated with 1,4-dioxane. It is reasonable to assume that many people exposed through their personal care products might also be exposed to 1,4-dioxane residues through cleaners, paints, dyes, or other consumer products. Those same individuals may also be exposed to 1,4-dioxane through drinking water, or may live in a community close to where 1,4-dioxane is processed, manufactured or disposed of. As such, even those "de minimis" exposures from 1,4-dioxane contamination can add up and contribute to an individual's aggregate exposure. Thus, these exposures should be included in the scope of risk evaluations so that EPA can more accurately gauge overall exposure and control risks.

Identifying hazards to "exposed individuals and populations"

EWG encourages EPA to keep in mind that the appropriate processes and procedures to identify susceptible and highly exposed populations may be unique to each substance evaluated. For example, legacy uses of a substance may have disproportionately contaminated particular communities, or exposure to a substance may pose unique health risks for fetal or childhood development. Consequently, EWG urges the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. EWG also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment.[27]

When EPA identifies "any potentially exposed or susceptible subpopulations" and "the hazards to health and the environment that EPA plans to evaluate," the agency should conduct outreach to communities likely to be home to potentially exposed or susceptible subpopulations. These communities may possess crucial information about hazards that the agency may itself lack. For

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[25] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 21 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf ("The extent that manufacturers or processors apply controls or processes to minimize or remove 1,4-dioxane in surfactants during manufacture or before formulation in consumer products is unknown and likely varies by sector.")

[26] *Id.*("manufacturers can apply controls to minimize the formation of 1,4-dioxane or remove most of the 1,4-dioxane present in these products through a vacuum stripping process").

[27] Envtl. Protection Agency, EJ 2020 Action Agenda: EPA's Environmental Justice Strategy, https://www.epa.gov/environmentaljustice/ej-2020-action-agenda-epas-environmental-justice-strategy (last visited Sept. 19, 2017).

example, as highlighted in the comments submitted by Earthjustice et al. in March,[28] such communities are in the best position to inform EPA about nursing homes or schools located near sites that increase the likelihood of their exposures to the chemical. Additionally, workers may be best able to identify real-world occupational exposures to chemicals, including roles and responsibilities that create highly exposed subgroups within their ranks. Other federal, state, and local regulatory authorities may also possess information necessary to establishing the proper scope of a risk assessment. For example, the California EPA has developed child-specific risk values for certain chemicals like atrazine and chlorpyrifos. Those values compare children's susceptibility to adults' by specifically examining child-specific routes of exposure.[29] EPA should review California EPA's approach and adopt its risk values as appropriate, and incorporate information from the analysis California EPA has already completed.

Aggregate and cumulative exposures

As part of a risk assessment, EPA is required to describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered.[30] As emphasized in the above sections, EWG strongly believes that considering the *aggregate* exposures will provide a more robust analysis of the total risk a chemical poses, and that EPA's scoping documents should reflect consideration of those aggregate exposures.

To properly assess aggregate exposures, EPA must consider exposures throughout the lifecycle of the chemical from all routes and pathways, including exposures from conditions of use not regulated by TSCA. This includes exposures from food, drinking water, pesticides, and personal care products, even if those uses are not specifically regulated during section 6(a) rulemaking. EWG emphasizes that this approach should include aggregate exposures from trace contaminants, such as asbestos fibers sometimes found in talc products,[31] or 1,4-dioxane in cleaning and personal care products that contain ethoxylated ingredients.[32]

When possible, EPA should also consider cumulative exposures when scoping a risk evaluation. EPA has explicit authority to order testing and prescribe protocols and methodologies for a number of health and environmental effects – including "cumulative or synergistic effects."[33] Considering cumulative exposures is in line with EPA's priorities and consistent with the best practices for risk evaluations. In *Framework for Cumulative Risk Assessment* (2003), EPA states,

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[28] Alaska Community Action on Toxics, et al., Comments on Scope of the Risk Evaluations for the First Ten Chemicals Under the Toxic Substances Control Act (Mar. 15, 2017).
[29] Cal. EPA, Office of Envtl. Health Hazard Assessment, Child-Specific Reference Doses Finalized to Date, http://oehha.ca.gov/risk-assessment/chrd/table-all-chrds (Jun. 22, 2010).
[30] 15 U.S.C. § 2605(b)(4)(F)(ii).
[31] Ronald Gordon, et. al., Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women, 20 Int'l J. of Occupational and Envt'l Health 318 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164883.
[32] Agency for Toxic Substances & Disease Registry, Public Health Statement for 1,4-Dioxane, Toxic Substances Portal (April 2012), https://www.atsdr.cdc.gov/phs/phs.asp?id=953&tid=199.
[33] 15 U.S.C. § 2603(b)(2)(A).

"Assessing cumulative risk through complex exposures is one of the Agency's high priorities…and it is germane and of great interest to all program and regional offices."[34]

Considering cumulative exposures is important because people and vulnerable subpopulations can be exposed to multiple chemicals and stressors that contribute to the same adverse health effects. The National Academy of Sciences (NAS) has noted the need to evaluate the cumulative effects of phthalates and also pointed to the fact that lead and mercury can collectively affect brain development.[35] Additionally, cumulative exposures to multiple carcinogenic solvents (TCE, 1,4-dioxane, methylene chloride and perchloroethylene) via air and drinking water may pose unique risks for people living near sites with industrial contamination. Taking such cumulative impacts into consideration would improve current assessments, and to the extent possible should be included in scoping.

EPA may consider collective exposure to groups of similar chemicals, and use the Adverse Outcome Pathway framework and database[36] to identify where cumulative effects may be an issue. EPA should follow the cumulative risk assessment process recommended by the National Academy of Sciences (NAS) in their Phthalates and Cumulative Risk Report.[37] When specific information is not available, EPA may use default values to account for cumulative exposures.

Conclusion

EWG appreciates the opportunity to comment on the scoping documents for the first 10 TSCA substances. We hope that these comments will help EPA to reevaluate the scoping documents of the first 10 TSCA substances so that they address fully the ways in which vulnerable and chemically over-burdened populations around the country are placed at risk by these chemicals. We look forward to continuing to participate in EPA's risk evaluation and risk management efforts under TSCA. Should you have any additional questions, please feel free to reach out to Melanie Benesh, Legislative Attorney at EWG, 202-939-0120, mbenesh@ewg.org.

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[34] Envtl. Protection Agency, Framework for Cumulative Risk Assessment, p. xi https://www.epa.gov/sites/production/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (last accessed Sept. 19, 2017).

[35] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508.

[36] Adverse Outcome Pathway Knowledge Database, Org. for Econ. Co-Operation & Dev., http://aopkb.org/ (last visited March 20, 2016).

[37] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508..

Message

From: Strauss, Linda [Strauss.Linda@epa.gov]
Sent: 12/20/2017 1:52:45 PM
To: Beck, Nancy [Beck.Nancy@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]
Subject: NYT press response on 3 chems

I sent our response last evening – still awaiting OPA approval. Story has already run.

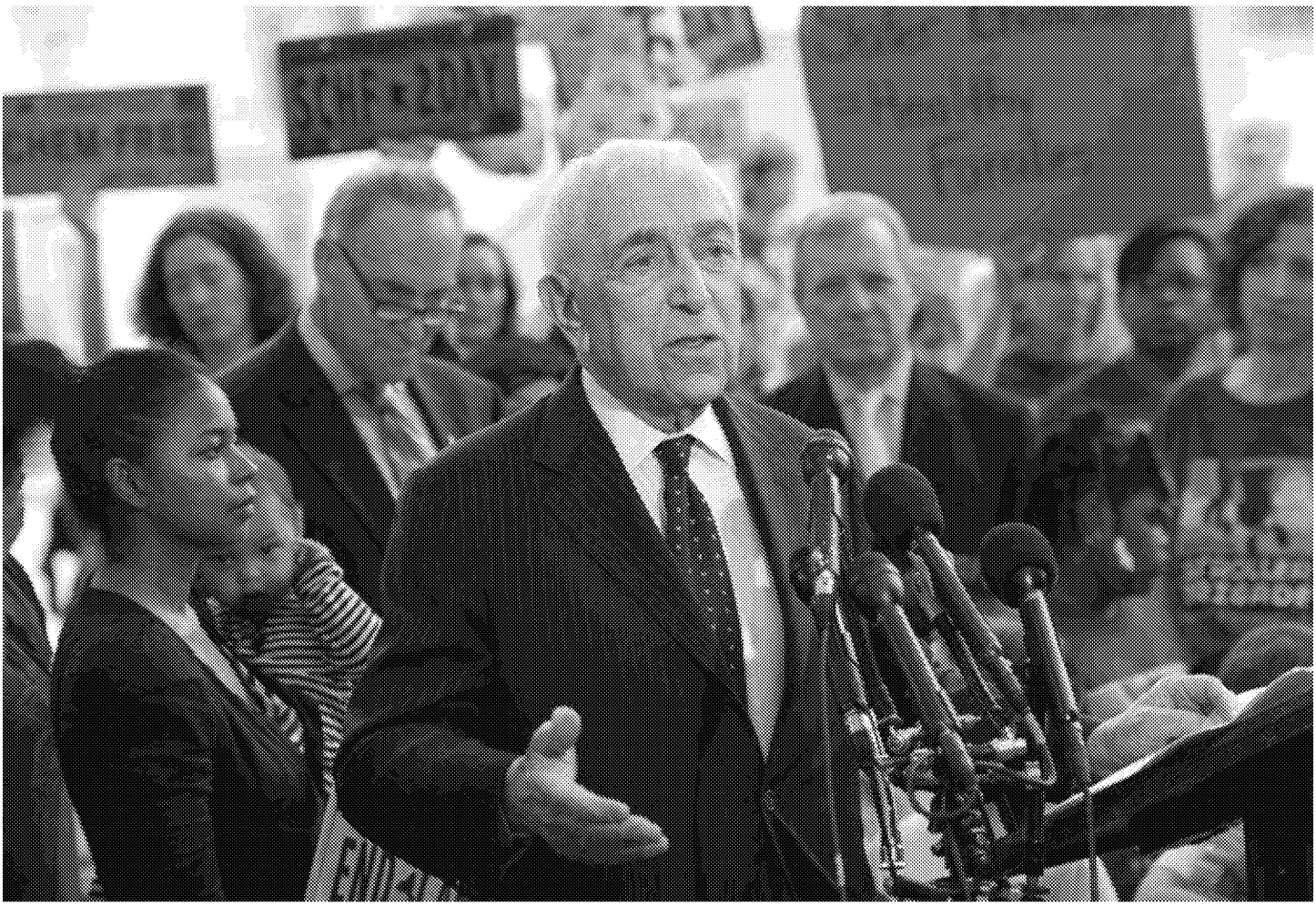
From: Daguillard, Robert
Sent: Wednesday, December 20, 2017 8:46 AM
To: Strauss, Linda <Strauss.Linda@epa.gov>
Subject: RE: LINDA: Morning check-in, 20 December 2017

Follow-up. The NY Times story:

E.P.A. Delays Bans on Uses of Hazardous Chemicals

By SHEILA KAPLANDEC. 19, 2017

Photo



Senator Frank Lautenberg, Democrat of New Jersey, on Capitol Hill in 2012, a year before his death. He urged the stricter regulation of toxic chemicals. CreditChris Maddaloni/CQ Roll Call, via Getty Images

The Environmental Protection Agency will indefinitely postpone bans on certain uses of three toxic chemicals found in consumer products, according to an update of the Trump administration's regulatory plans. Critics said the reversal demonstrated the agency's increasing reluctance to use enforcement powers granted to it last year by Congress under the Toxic Substances Control Act.

E.P.A. Administrator Scott Pruitt is "blatantly ignoring Congress's clear directive to the agency to better protect the health and safety of millions of Americans by more effectively regulating some of the most dangerous chemicals known to man," said Senator Tom Carper, Democrat of Delaware and the ranking minority member on the Senate Environment and Public Works committee.

The E.P.A. declined to comment. In a news release earlier this month, the agency wrote that its "commonsense, balanced approach carefully protects both public health and the environment while curbing unnecessary regulatory burdens that stifle economic growth for communities across the country."

Agency officials dropped prohibitions against certain uses of two chemicals from the administration's Unified Agenda of Regulatory and Deregulatory Actions, which details short- and long-term plans of the federal agencies. The third ban was dropped in the spring edition of that report.

The proposed bans targeted methylene chloride and N-methylpyrrolidone (NMP), ingredients in paint strippers, and trichloroethylene (TCE), used as a spot cleaner in dry-cleaning and as a degreasing agent.

Under an overhaul of the Toxic Substances Control Act last year, the E.P.A. initially is reviewing the risks of ten chemicals, including other uses of these three. The updated law is known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act, named after the late New Jersey senator who had long championed an overhaul of the loophole-ridden toxic substances law.

The revised law had strong bipartisan support. The Senate passed the measure on a voice vote; the House approved it 403 to 12. The intention was to give the E.P.A. the authority necessary to require new testing and regulation of thousands of chemicals used in everyday products, from laundry detergents to hardware supplies.

E.P.A. Administrator Scott Pruitt testifying before a House committee earlier this month. The E.P.A. has declined to pursue bans on certain uses of three toxic chemicals. CreditPete Marovich/Getty Images

In a compromise that disappointed some environmental advocates, the law required the E.P.A. to examine about 20 chemicals at a time, for no longer than seven years per chemical. But the law expressly allowed for faster action on high-risk uses of methylene chloride, NMP and TCE.

Public health experts had been pushing for faster review of methylene chloride-based paint strippers after several deaths from inhalation, among them a 21-year-old who died recently after stripping a bathtub.

It has been several years since the E.P.A. first declared these applications of the three chemicals to be dangerous. The agency itself has found TCE "carcinogenic to humans by all routes of exposure" and has reported that it causes developmental and reproductive damage.
"Potential health concerns from exposure to trichloroethylene, based on limited epidemiological data and evidence from animal studies, include decreased fetal growth and birth defects, particularly cardiac birth defects," agency officials noted in 2013.
Methylene chloride is toxic to the brain and liver, and NMP can harm the reproductive system.

Michael Dourson, President Trump's nominee to oversee the E.P.A.'s chemical safety branch, in 2010 represented the Halogenated Solvents Industry Alliance before the E.P.A., which was considering restrictions on TCE.

Mr. Dourson, who withdrew his name from consideration last week, had been working as an E.P.A. adviser while awaiting confirmation. The agency did not respond to a query about whether Mr. Dourson had been involved in the evaluation of TCE.

The E.P.A. now describes the enforcement actions regarding TCE, methylene chloride and NMP as "long-term actions" without a set deadline.

"The delays are very disturbing," said Dr. Richard Denison, lead senior scientist of the Environmental Defense Fund. "This latest agenda shows that instead of using their expanded authorities under this new law, the E.P.A. is shoving health protections from highly toxic chemicals to the very back of the back burner."

Representative Frank Pallone, Democrat of New Jersey and the ranking minority member of the House Energy and Commerce committee, agreed, saying, "These indefinite delays are unnecessary and dangerous."

"The harmful impacts of these chemicals are avoidable, and E.P.A. should finalize the proposed rules as soon as possible," he added.

From: Daguillard, Robert
Sent: Wednesday, December 20, 2017 8:34 AM
To: Strauss, Linda <Strauss.Linda@epa.gov>
Subject: LINDA: Morning check-in, 20 December 2017

Good morning Linda,

A few things:

- Pat Rizzuto has already published her story on asbestos – text follows these bullet points. She says she welcomes whatever we can send her, but will not update the already published text.
- The responses to the New York Times on TCE rulemaking await approval; The reporter has already published her story (link and text in a subsequent e-mail).
- Will we hold a public meeting during the glyphosate draft human health assessment comment period early next year?

BLOOMBERG BNA; PAT RIZZUTO:

EPA Reviews Contested Asbestos Uses in Oil, Chemical Production

Snapshot
• Oil drillers', chemical makers' use of asbestos probed
• In January, EPA to release scope of asbestos uses, exposures it will review

By Pat Rizzuto

Oil drillers' and chemical manufacturers' use of equipment made with asbestos is being probed by the EPA as agency officials decide whether uses of the mineral may be restricted.

The Environmental Protection Agency has met with American Friction Inc., the Branham Corp., the Chemours Co., the Occidental Chemical Corp., and other companies in recent months on the topic. These companies were queried about their importation or use of asbestos, according to meeting summaries.

The EPA is using this information to review which uses, exposures, and potentially exposed populations it will examine. Its goal is to decide whether the use of and exposure to the cancer-causing mineral poses an unreasonable risk. The review is occurring in the wake of findings from European regulators that 14 percent of more than 200 products tested contained

asbestos.

The scope of the EPA's risk evaluation and the questions it aims to answer will be in a "problem formulation" document set for release by the end of January 2018, Jeffery Morris, director of the EPA's Office of Pollution Prevention and Toxics, said Dec. 13 at a Society for Risk Analysis meeting.
The risk evaluation must be complete by mid-2020 under deadlines set by the Toxic Substances Control Act amendments of 2016.

If the EPA concludes that asbestos poses unreasonable risks, the agency could restrict or ban its importation or products that contain it.

Remediation Specialists Troubled

The EPA has not said what it will do with the recently gathered information, but a preliminary plan it released in June troubled asbestos remediation professionals along with organizations upset by the deaths asbestos has caused.

"We would see the exposures of most concern to us totally ignored," Andrew Oberta, an asbestos remediation consultant based in Austin, Texas, told Bloomberg Environment.

Oberta's company, the Environmental Consultancy, was among dozens of groups that said the EPA's preliminary plan would ignore the ongoing presence of asbestos in insulation, ceiling tiles, vinyl flooring, and other construction materials. People can be exposed as long as those products are in place, they said.

If the EPA ignores these ongoing exposures, its resulting risk evaluation likely wouldn't find problems, thus negating "the need for regulations and precautions to control the hazard," Oberta wrote in comments to the agency.

Asbestos Spurs Attention

Of the 10 chemicals EPA is reviewing, industry's ongoing uses of asbestos has stirred the most controversy as evidenced by the number of meetings, data submissions, and comments filed, according to EPA dockets.

The interest in asbestos is expected because of its known potential to cause cancer and lung disease, and because of long-standing frustration over the EPA's inability to ban a carcinogen. That fact was a major driver prompting Congress to amend TSCA.

In 1991, the U.S. Court of Appeals for the Fifth Circuit overturned the agency's 1989 rulemaking that would have banned multiple uses of asbestos (Corrosion Proof Fittings v. EPA).

Neither the EPA, American Friction, which specializes in oilfield equipment, Chemours, which uses asbestos-containing sheet gaskets to make titanium dioxide, nor Branham Corp., which imports gaskets and other industrial equipment for chemical and petrochemical industries, returned Bloomberg Environment's calls and emails seeking details on the information they discussed.

Legal Imports, Uses

The companies legally import and use asbestos. A few companies—Occidental Chemical Corp., Olin Corp., and Westlake Chemical Corp.—import large quantities of the raw mineral.

In 2016, the U.S. imported 705 metric tons (1.55 million pounds), according to data from the U.S. International Trade Commission. These companies use asbestos in special equipment that produces chlorine and caustic soda.

The EPA knows or suspects that many imported products contain asbestos, in addition to the raw mineral.

These include sheet gaskets, which seal equipment and are used by chemical manufacturers; brake blocks used by the oil industry; clothing for steel mill, welding shop, and other workers in hazardous environments; and building materials, according to an EPA use and market profile.

American Friction imported 46 shipments of brake blocks between July 1, 2007, and Dec. 14, 2017, according to information from Panjiva Inc., which compiles global trade data from U.S. government and other sources.

Buenos Aires-based Industries Brake Systems Argentina was the sole supplier of these brake blocks. Whether the blocks contain asbestos and how much isn't available from the import records.

"The import volume of products containing asbestos is not known," the EPA said in its preliminary assessment plan.

EU Identifies Sources

Other products not yet identified by the EPA also could be a source of asbestos, based on recent enforcement efforts in the European Union.

The European Chemical Agency's Enforcement Forum announced in November the results of its testing of 213 products for asbestos, which a 2016 restriction prohibits from being added to products.

Of those, 29, or 13.6 percent, had asbestos. The most frequent products containing it were catalytic heaters (20). Other products included thermos flasks (3), brake pads (2) and cement (2), according to data the agency provided to Bloomberg Environment.

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HSIA
halogenated solvents industry alliance, inc.

September 19, 2017

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: Trichloroethylene [EPA-HQ-OPPT-2016-0737]
Tetrachloroethylene [EPA-HQ-OPPT-2016-0732]
Methylene Chloride [EPA-HQ-OPPT-2016-0742]
Carbon Tetrachloride [EPA-HQ-OPPT-2016-0733]

Dear Sirs:

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) amended the Toxic Substances Control Act (TSCA) and established several regulatory timelines. Under TSCA § 6(b)(4)(D), EPA released scoping documents for the first ten chemicals targeted for evaluation under LCSA, including the chlorinated solvents trichloroethylene (TCE), tetrachloroethylene (perchloroethylene or PCE), and methylene chloride (dichloromethane or DCM). The general comments included in this submission are also applicable to the scoping document for carbon tetrachloride (CTC).

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers, distributors and users of chlorinated solvents. HSIA appreciates the opportunity to comment on problem formulation for the above-referenced scoping documents, as solicited in the notice announcing their release. 82 Fed. Reg. 31592 (July 7, 2017). In that notice, EPA acknowledged that the initial scoping documents did not achieve the quality anticipated for future scoping documents:

> "The first 10 chemical substances were not subject to prioritization, the process through which EPA expects to collect and screen much of the relevant information about chemical substances that will be subject to the risk evaluation process. As a result, EPA had limited ability to process all the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. Hence, the scope documents for the first 10 chemicals are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on drafts of these scope documents, as it intends to do for future scope documents."

One of the challenges for EPA in developing the required scoping documents was doing so prior to release of the final *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (Risk Evaluation Rule)*, 82 Fed. Reg. 33726 (July 20, 2017). Due to the acknowledged limitations of the initial scoping documents, EPA announced that it would:

> "publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals."

Typically, as will be discussed below, EPA treats Planning and Scoping and Problem Formulation as separate, albeit iterative, activities. The above statement indicates that EPA clearly has concerns with the quality of the Planning and Scoping element released in June and hopes to address those concerns through creation of a Problem Formulation document. Both elements are important in designing a credible risk assessment (or risk evaluation under LCSA). Recognizing that aspect, HSIA is pleased to submit the following comments for consideration by EPA in its development of the problem formulation documents for the four chlorinated organics (TCE, PCE, DCM, and CTC) found on the initial list of 10 chemicals under consideration.

General Recommendation

HSIA would strongly recommend that, in development of the problem formulation documents for the four chlorinated organics, EPA give serious consideration to its own guidance document *Framework for Human Health Risk Assessment to Inform Decision Making*. Although briefly mentioned in the Risk Evaluation Rule, there is no mention of the document in the June scoping documents for the four chlorinated compounds. We find this surprising, as application of the framework would appear to address many of the limitations acknowledged by EPA. As summarized in the 2014 document:

> "[t]he Framework for Human Health Risk Assessment to Inform Decision Making lays out a Framework for conducting human health risk assessments in support of decision making at EPA. It focuses on the planning and scoping and problem formulation steps, drawing on NRC (2009) and other advisory groups, and EPA experience. For example, the Framework addresses recommendations in the Silver Book (NRC 2009) on assuring the utility of risk assessment, which the Framework terms as being fit for purpose. . . [T]he NRC's 1983 four-step risk assessment paradigm is maintained, but there is increased emphasis on interaction between risk assessors and risk managers in planning the assessment to maximize utility. Emphasis on utility is maintained throughout the process, beginning with planning and scoping and continuing through the evaluation of the applicability of the risk assessment in informing decisions."

and

> "[a]pplication of the Framework, with its emphasis on problem formulation and the utility of the risk assessment, ultimately will result in better, more transparent choices among risk management options. This Framework builds on Agency guidelines, policies and guidance and is directed at improving risk assessment products but does not overturn or in any way change existing science policy decisions."

Specific Recommendations

Although the four chlorinated organics from the initial list of ten chemicals under consideration were not subjected to the LCSA prioritization process anticipated for chemicals considered in the future, it must be noted that all have been in commerce for decades and all should be considered "data-rich." As such, they all have a history of already being heavily regulated/controlled under a variety of existing federal and state programs. This makes them somewhat unique, particularly when compared against chemicals newly introduced into commerce, and raises some interesting problems in evaluating them under LCSA.

As mentioned earlier, the initial scoping documents for the four chlorinated organics were released prior to issuance of the Risk Evaluation Rule. In the preamble to that rule, which became effective on

September 18, EPA provided clarification on several issues that were problematic/unclear in the draft version released under the previous administration. In the following sections, HSIA addresses several of these specific issues in hopes that EPA will consider them during development of the problem formulation documents.

EPA's interpretation of its regulatory mandate under LCSA

In the Risk Evaluation Rule, EPA's clarified its regulatory mandate under LCSA:

> "EPA interprets the mandates under section 6(a)–(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur. . . ."

HSIA agrees with this position. As will be seen in several of the following recommendations, further broadening of that mandate for chemicals that are already subjected to extensive regulation presents serious conflicts both in assessing potential human health and environmental risks and in any subsequent risk management decisions. The focus should be restricted to chemicals in commerce from this point forward.

EPA should use discretion in its selection of conditions of use

One of the most contentious issues associated with the evaluation of risk under LCSA is "conditions of use." The issue focuses on the question "should any/all actual/potential uses of a chemical in the past/present/future be considered in the risk evaluation?" LCSA does not require the Agency to conduct full risk evaluations based on all conditions of use and nowhere in the law is "conditions of use" preceded by "all." Expansion of the term "conditions of use" beyond the intent of Congress may distract from and negatively impact EPA's ability to conduct meaningful risk evaluations in a timely manner.

EPA should exclude certain *de minimis* conditions of use

The four chlorinated organics included on the initial list are all used as intermediates in the synthesis of other chemicals. These are the largest uses of CTC and TCE. Such feedstock use takes place within closed systems in restricted-access facilities where workers are operating under Occupational Safety & Health Administration (OSHA) regulations with appropriate personal protective equipment (PPE). Given the nature of the chlorinated organics, a leak detection and repair (LDAR) program is typically in place and fugitive emissions are monitored. The only potential human exposure would be to on-site workers, whose risks are managed under a facility's health and safety program, which falls under the jurisdiction of OSHA. Potential off-site exposures would only occur at or beyond the facility fence-line, and air modeling of fugitive emissions typically shows maximum air concentrations occurring very close to the release point (*i.e.*, within the facility). In the preamble to the Risk Evaluation Rule, EPA addresses the issue of *de minimis* exposures such as these with the following rather ambiguous language:

> "EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only '*de minimis*' exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate."

Given our understanding of the use of these solvents as intermediates, HSIA believes there is a sufficient basis to exclude this "condition of use" from further consideration in the risk evaluation.

EPA should consider a tiered approach to address *de minimis* and/or heavily regulated exposures

For those situations where EPA is not comfortable excluding certain "conditions of use" based on anticipated *de minimis* exposures, HSIA recommends that the Agency consider a tiered approach for screening potential risks as an initial step in the risk evaluation. Although our preference would certainly be to exclude those *de minimis* and/or heavily regulated "conditions of use" during the scoping/problem formulation stage, we support EPA's recognition in the Risk Evaluation Rule that in order to efficiently carry out the LCSA Congressional mandate, EPA must maintain the flexibility to issue a decision on specific "conditions of use" in a tiered, staged approach.

Legacy sources of exposure should not be addressed under LCSA

HSIA recommends that legacy sources of exposure should be excluded from the risk evaluation process under LCSA. Legacy sources of exposure typically refer to historical releases of a chemical to the environment associated with misuse or disposal. Although legacy environmental sources of exposure certainly exist for the four chlorinated organics, they have been effectively managed for decades under various federal programs (*i.e.*, CERCLA, RCRA, CAA, etc.). Many states also have stringent programs for addressing legacy contamination from these chemicals. Management of legacy contamination through the various federal and state programs is already risk-based and adding an additional risk-management program to the existing mix would be duplicative and not needed. The following statement from the preamble to the Risk Evaluation Rule indicates that EPA feels it could "exercise its discretion" on decisions relating to exclusion of a particular condition of use.

> "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks."

From a practical perspective, it is difficult to conceive how risks from a legacy source of exposure would even be managed under LCSA. For the four chlorinated organics, once a legacy exposure source (*i.e.*, existing environmental contamination) is discovered, responsibility for management of any human health or environmental risk would be assumed by the state. If the source was sufficiently large and generated a sufficiently high Hazard Ranking Score (HRS), it could be classified as a Superfund site under CERCLA.

Protection from workplace exposures to chemicals is the primary responsibility of OSHA, not EPA

As noted above, EPA has exclusionary discretion for "a condition of use [*i.e.*, exposure] that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks." As originally enacted and as updated by LCSA, TSCA requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."[1] It has been clear since passage of the Occupational Safety and Health Act in 1970 that workplace protection is the primary responsibility of OSHA.

The LCSA eliminated the requirement in TSCA § 6(a) that EPA protect "against [unreasonable] risk using the least burdensome requirements," but did not materially change the existing framework that

[1] TSCA § 9(d).

requires unreasonable risks to be addressed under statutory authority other than TSCA wherever possible. EPA's longstanding interpretation of this framework is as follows:

> "Under section 9(a)(1) of TSCA, the Administrator is required to submit a report to another Federal agency when two determinations are made. The first determination is that the Administrator has reasonable basis to conclude that a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. The second determination is that the unreasonable risk may be prevented or reduced to a sufficient extent by action taken by another Federal agency under a Federal law not administered by EPA. Section 9(a)(1) provides that where the Administrator makes these two determinations, EPA must provide an opportunity to the other Federal agency to assess the risk described in the report, to interpret its own statutory authorities, and to initiate an action under the Federal laws that it administers.
>
> "Accordingly, section 9(a)(1) requires a report requesting the other agency: (1) To determine if the risk may be prevented or reduced to a sufficient extent by action taken under its authority, and (2) if so, to issue an order declaring whether or not the activities described in the report present the risk described in the report.
>
> "Under section 9(a)(2), EPA is prohibited from taking any action under section 6 or 7 with respect to the risk reported to another Federal agency pending a response to the report from the ether Federal agency. There would be no similar restriction on EPA for any risks associated with a chemical substance or mixture that is not within the section 9(a)(1) determinations and therefore not part of the report submitted by EPA to the other Federal agency."[2]

It was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. When TSCA was enacted in 1976, Representative James Broyhill of North Carolina indicated that "it was the intent of the conferees that the Toxic Substance [Control] Act not be used, when another Act is sufficient to regulate a particular risk."[3] TSCA § 9(a) is substantively unchanged by the LCSA. The House Energy and Commerce Committee Report states: "H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals," and further clarifies that "while § 5 makes no amendment to TSCA § 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety."[4]

EPA applied this statutory directive in determining that the risk from 4,4' methylenedianiline (MDA) could be prevented or reduced to a significant extent under the OSH Act, and referring the matter for action by OSHA.[5] And in an analysis of TSCA § 9, EPA's Acting General Counsel concluded that

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[2] 4,4'-Methylenedianiline; Decision to Report to the Occupational Safety and Health Administration, 50 Fed. Reg. 27674 (July 5, 1985). EPA also has acted under § 9(a) to refer 1,3-butadiene and glycol ethers to OSHA, 50 Fed. Reg. 41393 (Oct. 10, 1985) and 51 Fed. Reg. 18488 (May 20, 1986), respectively, and to refer dioxins in bleached wood pulp and paper products to the Food and Drug Administration, 55 Fed. Reg. 53047 (Dec. 26, 1990).

[3] 122 Cong. Rec. H11344 (Sept. 28, 1976)

[4] H. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28.

[5] 50 Fed. Reg. 27674 (July 5, 1985).

"Congress expected EPA – particularly where the Occupational Safety and Health Act was concerned – to err on the side of making referrals rather than withholding them."[6]

If EPA were to identify a category of exposure deemed to present a risk that is unreasonable, these considerations indicate that referral under § 9(a) would be the appropriate course.[7] It is clear from Section 9(a) that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks.

EPA codified this principle in the Risk Evaluation Rule, 40 C.F.R. §702.39. EPA should adopt the OSHA permissible exposure limits (PELs) as the appropriate screening levels for potential risks to workers. If the 90th percentile estimates from the 8-hour time-weighted average (TWA) exposure concentrations are at or below the OSHA PELs, EPA should conclude a condition of no significant risk for worker exposures. However, it is possible that EPA could, if scientifically appropriate, decide to apply more recent American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) to evaluate potential risks to workers.

Occupational exposure limits, such as OSHA PELs and ACGIH TLVs, are derived to be protective for occupational exposures. The values are typically based on occupational epidemiology studies and, therefore, are especially relevant for worker populations. For example, occupational studies by their very nature include consideration of the healthy worker effect.[8] Occupational exposure limits also consider other factors unique to the workplace, such as technical feasibility. In general, occupational exposure limits should be considered protective for worker exposures. Such limits and their bases should be part of worker risk evaluations under the new TSCA.

Risk evaluations conducted under LCSA should be state-of-the-art

There have been significant developments in the science of risk assessment and in our understanding of mode of action for cancer and other apical endpoints in recent years. HSIA is encouraged that EPA has acknowledged these developments in the Risk Evaluation Rule and appears committed to including them in risk evaluations conducted under LCSA. Many of these developments are the result of concerns with EPA's IRIS program. HSIA believes that the following are necessary components of a state-of-the-art risk evaluation and should be part of the problem formulation documents.

Systematic Review: Although several of the chemicals from the initial list of ten to be evaluated under the amended TSCA are relatively data-rich, it is essential that a systematic review be undertaken to ensure that all existing hazard data are considered. The IRIS evaluation of TCE, for example, was completed in 2011 and an examination of that document reveals that many of the studies referenced are now more than a decade old. Although EPA indicated that many of the principles of systematic review were considered

[6] Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2.

[7] As noted above, TSCA § 9(a) provides that if the Administrator has reasonable basis to conclude that an unreasonable risk of injury is presented, and he determines, in his discretion, that the risk may be prevented or sufficiently reduced by action under another federal statute not administered by EPA, then the Administrator shall submit a report to that agency describing the risk. In the report, the Administrator shall request that the agency determine if the risk can be prevented or sufficiently reduced by action under the law administered by that agency; if so, the other agency is to issue an order declaring whether the risk described in the Administrator's report is presented, and is to respond to the Administrator regarding its prevention or reduction. The Administrator may set a time (of not less than 90 days) within which the response is to be made. The other agency must publish its response in the Federal Register. If the other agency decides that the risk described is not presented, or within 90 days of publication in the Federal Register initiates action to protect against the risk, EPA may not take any action under § 6 of TSCA.

[8] A healthy worker effect is based on observations in occupational epidemiology studies that workers usually exhibit lower overall death rates than the general population because the severely ill and chronically disabled are ordinarily excluded from employment (Li *et al.* 1999).

during the TCE IRIS evaluation, there have been significant developments in that process over the past decade. At the very least, the systematic review should consider all existing hazard data and, consistent with current approaches, publish acceptance criteria, including criteria to assess study quality, which are then used in the selection of key studies.

HSIA would recommend that a similar approach be applied to exposure data used for the risk evaluation. For example, a systematic review of air monitoring data should exclude data generated prior to the effective date of a National Emission Standard for Hazardous Air Pollutants which limited the emissions of a particular chemical from covered sources. Although EPA provides a fairly lengthy discussion on systematic review in the preamble to the Risk Evaluation Rule, it did not codify a definition for systematic review. Many of the elements of systematic review do, however, appear in the codified definition of "weight of scientific evidence" provided below.

Consideration of Best Available Science: HSIA strongly endorses the use of best available science in risk evaluations conducted under LCSA. Although Section 702.33 of the Risk Evaluation Rule provides a detailed definition of "best available science," the overarching principal is science that is reliable and unbiased. Several of the chlorinated solvents have suffered from EPA's reliance on scientific studies that were considered substandard by the scientific community. HSIA is hopeful that EPA's commitment to consideration of best available science, when combined with a formal systematic review process, will yield risk evaluations that are reliable.

Consideration of New Data: HSIA supports EPA's position on the acceptance of new data for consideration in the risk evaluation.

> "EPA does not intend to preclude the generation of new scientific information to inform risk evaluations, however, as mentioned in the discussion of reasonably available information, the extent to which EPA will consider any newly generated information in a risk evaluation will depend on the statutory deadlines."

Application of Weight of Scientific Evidence Approach: As discussed above, Section 702.33 of the Risk Evaluation Rule defines "weight of scientific evidence" as:

> ". . . a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."

Similar language regarding the "weight of scientific evidence" was included in the scoping documents for TCE , PCE , DCM and CTC released in June 2017 [excerpt from the TCE scoping document follows]:

> "EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent."

Whether or not a definition for systematic review is codified in the Risk Evaluation Rule is less important than EPA's commitment to integrate the process into risk evaluations conducted under LCSA. HSIA strongly supports that commitment for both hazard and exposure data.

Peer Review: Although the proposed Risk Evaluation Rule only provided lip-service to the concept of peer review, HSIA strongly supports EPA's commitment to the peer review process as described in the preamble to the final rule:

> "In addition to any targeted peer review of specific aspects of the analysis, the entire risk assessment will also undergo peer review [emphasis added], as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination. "

EPA's commitment to the peer review process under TSCA has, to date, been uneven. Although the TSCA Work Plan Chemicals Assessment for TCE, conducted in 2012, was subjected to external peer review, the final document contained an exposure scenario (*i.e.*, condition of use) that was not even included in the draft. Despite lack of peer review for that condition of use, EPA used the results of the risk assessment as the basis for a proposed ban.

Public Comment Period: LCSA requires that EPA allow for no less than a 30-day public comment period on a draft risk evaluation, prior to publishing a final risk evaluation. HSIA recommends that EPA allow at a minimum a 60-day public comment period following release of the draft problem formulation documents given their obvious importance in setting precedent for the program moving forward. Indeed, a public meeting to review and discuss public comments on the draft problem formulation documents could greatly facilitate agreement on the final product (*i.e.*, the risk evaluation).

Clearly, the scenarios examined in the 2014 TSCA Work Plan Chemicals Assessments should be re-evaluated. Language in the scoping documents for TCE and DCM, released by EPA in June 2017, indicates that conditions of use previously evaluated in 2014 TSCA Work Plan Chemical Risk Assessments may not be re-evaluated under the Risk Evaluation Rule. HSIA urges EPA to reconsider this position as part of problem formulation, for several reasons. First, as already mentioned, between publication of the peer-reviewed draft assessment for TCE in 2012 and release of the final version in 2014, EPA introduced a new "condition of use" (*i.e.*, spot cleaning) which was not subjected to peer review. Second, the Risk Evaluation Rule, which promulgated the procedure(s) to be followed in conducting a risk evaluation to satisfy requirements under LCSA, was not published until July 20, 2017, three years after finalization of the Work Plan Chemical Assessments for TCE and MC. All significant "conditions of use" should be evaluated in compliance with the Risk Evaluation Rule, which requires significant aspects not addressed or applied in the previous risk assessments, such as consideration of best available science and application of a weight of the scientific evidence approach.

To facilitate EPA's review of these uses, HSIA is submitting comments on the earlier proposed rules (and related risk assessments) to the relevant dockets.

EPA's approach for evaluating environmental impacts under LCSA is problematic

Under LCSA, EPA is required to evaluate potential chemical impacts on the environment and HSIA has serious concerns about the approach described in the final Risk Evaluation Rule. The scoping documents for the four chlorinated organics state that:

> ". . . manufacturing, processing, use and disposal . . . . . can result in releases to air, water, sediment and soil. EPA expects to consider exposures to the environment and ecological receptors that occur via these exposure pathways or media . . . . . in conducting the risk evaluation . . . ."

The Risk Evaluation Rule appears to expand the potential scope for the evaluation of environmental impacts even further. Under §702.43(4) (*i.e.*, Considerations for environmental risk evaluations), the rule states:

> "For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance."

In addition to being concerned about the level of effort required to carry out such an activity, HSIA is concerned that such an evaluation would have to be location-specific. If, for example, EPA is interested in evaluating potential environmental impacts from a manufacturing facility, those impacts will have to be based on either measured or modeled media concentrations. The fate and transport of chemicals into air, soil, sediment, and surface water is known to be influenced by factors that are location- and site-specific and any adverse impacts will be applicable to that specific facility only. The air modeling of emitted chemicals from a manufacturing facility into environmental media surrounding that facility, for example, will be influenced by many factors, including local meteorology, terrain, proximity to surface water bodies, and distance to the facility boundaries, among others.

As described, the evaluation of environmental impacts under LCSA could result in a situation where a "condition of use" is found to be associated with unacceptable environmental impacts, yet the "condition of use" would only be relevant at a specific facility. That same "condition of use" could be acceptable at another facility operating under the exact same conditions, creating a real risk management dilemma.

* * * * * * * * * * * * *

HSIA appreciates the opportunity to provide these comments on this important step of problem formulation.

Respectfully submitted,

Faye Graul

Faye Graul,
Executive Director

September 19, 2017

EWG Comments on the Risk Evaluation Scoping for the First 10 Chemicals Under TSCA

Docket ID Nos.: EPA-HQ-OPPT-2016-0723 (1,4- Dioxane); EPA-HQ-OPPT-2016-0725 (Pigment Violent 29) EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene (also known as perchloroethylene)); EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride); EPA-HQ-OPPT-2016-0735 (Cyclic Aliphatic Bromide Cluster (HBCD)); EPA-HQ-OPPT-2016-0736 (Asbestos); EPA-HQ-OPPT-2016-0737 (Trichloroethylene (TCE)); EPA-HQ-OPPT-2016-0741 (1-Bromopropane); EPA-HQ-OPPT-2016-0742 (Methylene Chloride); and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone (NMP)).

The Environmental Working Group (EWG) is a nonprofit advocacy organization dedicated to improving environmental health. EWG has long advocated for stronger federal chemical regulations and spent over a decade advocating for reforms to strengthen the Toxic Substances Control Act (TSCA). The Frank R. Lautenberg Chemical Safety for the 21st Century Act (hereinafter "Lautenberg Act") for the first time will require the Environmental Protection Agency (EPA) to comprehensively review existing chemicals on the TSCA inventory—starting with 10 work plan chemicals, as required by section 6(b)(2)(A).[1] As the first chemicals assessed under the recently overhauled law, these first 10 assessments represent an early test of the strength of the new law. As such, it is important that the scopes of these first 10 chemical risk evaluations adequately consider the diverse uses of each chemical and the unique ways that vulnerable and chemically over-burdened populations may be at risk.

We submit these comments generally to apply to all 10 scoping documents released by EPA on June 22, 2017. The following comments are meant to assist EPA to strengthen the proposed scopes of the first 10 chemicals before it moves into the problem formulation phase of the risk evaluation process. In particular, EWG comments that EPA's scoping documents on the first 10 chemicals should be revised as needed to ensure they include:

- Reasonably foreseeable uses like accidents, misuses, and off-label uses
- The entire lifecycle of the chemical
- Exposures from non-TSCA uses
- Contaminants and low-concentration uses that contribute to overall exposure
- Exposures for which data is limited
- Risks to potentially exposed and susceptible populations
- Risks from aggregate and cumulative exposures

Accidents, misuses, and off-label uses

[1] 15 U.S.C. § 2605(b)(2)(A).

Pursuant to TSCA section 6(b)(4)(D), a chemical's scoping document should include "the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider."[2]

The Lautenberg Act defined "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[3] The plain language of this definition requires EPA to consider not only the intended and known uses of a chemical, but also any "reasonably foreseeable uses."

Reasonably foreseeable uses should include accidents like chemical spills and leaks that can contaminate air, water, and soil. The National Environmental Policy Act ("NEPA") highlights how "reasonable foreseeability" includes accidental releases in the context of environmental law. NEPA requires federal agencies to prepare an environmental impact statement ("EIS") for any proposed major federal action "significantly affecting the quality of the human environment."[4]

Other language in TSCA further underscores the intention to include accidental or inadvertent releases or exposures. The process for prioritizing chemicals requires EPA to consider "storage near significant sources of drinking water."[5] This is a clear reference to potential risks from accidental spills or leaks, or even criminal releases, into drinking water.

EWG is further concerned by EPA's stated intent to generally exclude "intentional misuses" from the scope of a chemical risk evaluation.[6] Reasonably foreseeable uses would also include foreseeable misuses, whether they are intentional or not. For example, a consumer may foreseeably misuse cleaning and other consumer products in several ways. A bathtub cleaner may also be used to clean the bathroom sink. A cleaner that is meant to be sprayed from 8 to 10 inches away may instead be sprayed from 3 inches away. Consumers and workers may apply more or less of a product than what is directed. Chemical facilities may intentionally improperly release or dispose of a chemical. These misuses are reasonably foreseeable and should be included in the scope of a risk evaluation.

Lifecycle of chemical, including legacy uses

Section 6(a) requires EPA to regulate when an unreasonable risk is posed by the "manufacture, processing, distribution in commerce, use, or disposal" of a chemical or "any combination such activities."[7] This makes clear that in the scope of a risk assessment, EPA must account for the entire lifecycle of the chemical, including risks during production, processing, distribution, recycling, and disposal, or any combination of those activities. It follows that the scope of EPA's risk evaluations should include both current and also legacy uses, as well as legacy disposal. As

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[2] 15 U.S.C. 2605 (b)(4)(D).
[3] 15 U.S.C. 2602(4).
[4] 42 U.S.C. § 4332(2)(C)(i).
[5] 15 U.S.C. § 2605(b)(1)(A).
[6] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).
[7] 15 U.S.C. 2605(a).

such, EWG is concerned by EPA's stated intention to focus on "uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal."[8]

This interpretation undermines the design of TSCA as a cradle-to-grave statute and is at odds with EPA's clear mandate to evaluate and regulate risks at the end of a chemical's lifecycle. Excluding legacy uses is also at odds with EPA's requirement to "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance."[9] To fully consider the frequency and number of exposures to a chemical, EPA must consider likely exposure from all sources—regardless of whether the exposure came from an ongoing or a legacy use.

Asbestos and the HBCD provide important examples. Both chemicals may be found in previously installed insulation and other building materials in homes, offices, schools and other buildings. They can be released if disturbed, creating an exposure risk. Thousands of American homes have asbestos-containing vermiculite insulation, and millions have HBCD-containing insulation board. As insulation ages, chemicals like HBCD and asbestos can migrate into household dust.

Building materials may also be improperly removed or disposed of, creating additional exposure risks. For example, in 2016, the Washington State Attorney General brought charges against a hotel owner for improper asbestos removal.[10] According to the news release, the owner lied about the extent of renovations in order to get around asbestos surveying and permit requirements. As a result, workers, inspectors, and people living near the hotel were all potentially exposed to unsafe levels of asbestos from legacy uses.

The prevalence of these legacy uses underscores the importance of including them in risk evaluations. Without considering exposure from legacy uses or disposal, EPA will be unable to assess the aggregate exposure because it will not have a complete picture of the "likely duration, intensity, frequency, and number of exposures to a chemical."

Consideration of non-TSCA uses

The requirement that EPA consider the "hazards, exposures, [and] conditions of use" in its scoping documents and also the "likely duration, intensity, frequency, and number of exposures" means that EPA must also consider uses covered by other agencies and statutes.

EWG is concerned by EPA's assertion that "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly

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[8] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017).
[9] 15 U.S.C. § 2605(b)(4)(F)(iv).
[10] Press Release, Washington State Office of the Attorney General, AG Files Criminal Charges Against Hotel Owner over Asbestos Removal (May 11, 2016), http://www.atg.wa.gov/news/news-releases/ag-files-criminal-charges-against-hotel-owner-over-asbestos-removal.

where the other agency has effectively managed the risks."[11] Even if another agency has taken steps to manage risk from a particular use, that doesn't mean the use does not contribute to exposure or that the risk has been eliminated. For example, many of the first 10 chemicals pose occupational risks that may be regulated by OSHA. However, oftentimes OSHA's regulations need to be updated or do not go far enough. For example, OSHA has a permissible exposure limit (PEL) for trichloroethylene, or TCE, but it is already 20 years old.[12] Additionally, even OSHA admits that many of its PELs are outdated and do not adequately protect workers from chemicals.[13] As such, action taken by OSHA should not be a basis for excluding occupational uses from a risk evaluation scope.

Likewise, several TSCA-regulated chemicals also have FDA-regulated uses. Although methylene chloride is primarily used as a paint stripper and remover,[14] FDA has also approved it as a food additive for uses including as a solvent in the extraction of caffeine from green coffee beans.[15] A person who uses a methylene chloride-based paint stripper may also drink decaffeinated coffee and could be exposed from both sources. 1,4-Dioxane, used industrially as a solvent and chemical stabilizer, is a well-known contaminant in personal care and other consumer products. A recent analysis by EWG found that as many as 8,000 personal care products contain ethoxylated ingredients manufactured through a process that may create 1,4-dioxane as a byproduct.[16] An individual exposed to 1,4-dioxane in an occupational setting would likely also be exposed to 1,4-dioxane through their personal care or cleaning products.

Finally, non-TSCA uses include uses regulated by EPA, but under other statutes. Several of the first 10 chemicals—including 1,4-dioxane, TCE, tetrachlorethylene (perc), methylene chloride, asbestos, and carbon tetrachloride—are known to contaminate drinking water systems, according to nationwide water testing results analyzed in EWG's recently released Tap Water Database.[17] These chemicals are detected in concentrations that exceed health guidelines in drinking water served to millions of Americans, sometimes in combination with each other due to a common industrial source. Of these contaminants, EPA has yet to set an enforceable drinking water standard for 1,4-dioxane. The Maximum Contaminant Levels set for carbon tetrachloride, TCE, tetrachlorethylene, and methylene chloride are all less health-protective than other standards or public health goals promulgated by EPA or other public health agencies such as the California Office of Environmental Health Hazard Assessment. Even so, EWG's analysis found drinking water violations in some drinking water systems that had levels of carbon tetrachloride, TCE,

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[11] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).

[12] Envtl. Protection Agency, Scope of the Risk Evaluation for Trichloroethylene, p. 32 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf

[13] U.S. Dep't of Labor, Occupational Safety and Health Administration, Permissible Exposure Limits—Annotated Tables, https://www.osha.gov/dsg/annotated-pels/ (last accessed Sept. 19, 2017).

[14] ATSDR, Toxicological Profile for Methylene Chloride, pp. 1-2, https://www.atsdr.cdc.gov/toxprofiles/tp14.pdf (last accessed March 7, 2017).

[15] 21 C.F.R. § 173.255(c).

[16] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

[17] Envtl. Working Grp., EWG's Tap Water Database, All Contaminants, https://www.ewg.org/tapwater/chemical-contaminants.php#.WcCifNN96CQ.

and tetrachlorethylene exceeding the MCLs. Because water contamination is so pervasive, and EPA's enforceable drinking water standards are often not sufficiently protective, EPA should always consider exposure from drinking water as part of its risk assessments.

These examples show that people are exposed to chemicals in myriad ways that often fall under the jurisdiction of different laws and different agencies. While EPA would only regulate some of those uses under TSCA, uses and exposures that occur outside of TSCA's jurisdiction contribute to an individual's aggregate exposure, and thus could contribute to an unreasonable risk of injury to health and must be considered.

Must be based on adequate information

EPA should not omit a condition of use from the scope of the risk assessment because data on that particular use is lacking. For example, EPA has insufficient information about the likely exposure of workers and people living in homes that use HBCD insulation. EPA also has limited information about 1,4-dioxane levels in products that contain ethoxylated ingredients. EPA should study exposures rather than make assumptions based on the limited data. After all, the law requires EPA to actively seek "reasonably available information" about conditions of use from stakeholders.[18]

"Reasonably available" is defined broadly in the final risk evaluation rule to include not only information EPA possesses, but also all information EPA can "reasonably generate, obtain, and synthesize for use in risk evaluations."[19] This would include information published in scientific journals and industry studies. It would also include information already collected by state governments or under foreign regulations like the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) in Europe. If EPA knows this information exists and was submitted to other governments, it should take measures to request the same information from the manufacturers or processors responsible for its submission. Additionally, EWG encourages EPA to rely on the appropriate use of defaults, or calculated uncertainty factors when specific information is missing. Finally, EPA has various tools under sections 4, 8(a), 8(c), 11 and 26(a) to order testing or solicit information as needed to fill data gaps.

Exposure from contaminants or impurities

EWG is concerned by EPA's stated intent to generally exclude impurities and other "de minimis" exposures from the scope of its risk evaluations.[20]

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[18] 15 U.S.C. § 2625(k) ("The Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator."); 15 § 2605(b)(4)(F)(i).

[19] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33748 (July 20, 2017) (to be codified at 40 C.F.R. pt. 702.33).

[20] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017)("EPA may choose not to include a particular impurity within the Scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the impurity would be 'de minimis' or otherwise insignificant.")

This general exclusion falsely equates de minimis exposures with low risk. It disregards the significant body of evidence that hormone disruptors and developmental toxicants may cause adverse effects at very low doses, and ignores the possibility of nonmonotonic dose-response curves. The pharmaceutical literature is rife with examples of nonmonotonicity, timing and age-group specific toxicity concerns.[21] Furthermore, even de minimis exposures contribute to an individual's aggregate exposure to a chemical.

An important example is 1,4-dioxane. 1,4-Dioxane is a well-known impurity that occurs as a byproduct of the ethoxylation process. In the scoping document for 1,4-dioxane, EPA has indicated it will exclude these uses from the scope of its evaluation. Specifically, EPA states that:

> In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane.[22]

This approach is backwards. 1,4-Dioxane is a likely carcinogen and is associated with several other health effects, including liver and kidney damage, lung irritation, and eye, nose, and throat irritation.[23] Whether the presence of 1,4-dioxane in a product is intentional or the result of contamination does not change the potential health risks. Furthermore, it makes more sense to examine the risks from 1,4-dioxane formation in the context of the risk evaluation on 1,4-dioxane when EPA will be looking at other routes of 1,4-dioxane exposure and specifically analyzing the risks from 1,4-dioxane.

Several chemicals form 1,4-dioxane as part of the ethoxylation process. An analysis of EWG's Skin Deep database found that as many as 8,000 products contained ethoxylated ingredients that create 1,4-dioxane as a byproduct during manufacturing.[24] Presumably, future EPA risk evaluations on any of those ethoxylated chemicals will be focused on the risks posed by those chemicals themselves, with 1,4-dioxane formation considered only as a secondary issue. Furthermore, evaluating 1,4-dioxane formation as part of the risk evaluation for each ethoxylated chemical separately—each of which could be years or decades apart—would give EPA a disjointed and incomplete picture of the real problem.

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[21] See, e.g., Non-monotonic Dose Response Curves, Our Stolen Future, http://www.ourstolenfuture.org/NewScience/lowdose/nonmonotonic.htm (last visited Sept. 19, 2017).
[22] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 8 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf (emphasis added).
[23] ATSDR, Toxicological Profile for 1,4-dioxane, Relevance to Public Health, p. 2, https://www.atsdr.cdc.gov/toxprofiles/tp187-c2.pdf (last accessed Sept. 19, 2017).
[24] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

As EPA admits,[25] there is little information about how widespread contamination from 1,4-dioxane is in consumer products with ethoxylated ingredients. Because it's not intentionally added it does not need to be listed on product labels, and companies are not required to measure or disclose levels of 1,4-dioxane in their products. As such, there is little way to know if 1,4-dioxane is present and, if so, at what levels. While manufacturers can take steps to minimize 1,4-dioxane formation or vacuum strip it from products, manufacturers are also not required to report if they are doing so.[26] EPA should not make assumptions based on what it does not know, but should instead study the issue.

Without more information, EPA cannot assume that 1,4-dioxane exposures through personal care and other consumer products are minimal and not a concern. Americans use several different kinds of personal care products every day, many of which contain ethoxylated ingredients and could be contaminated with 1,4-dioxane. It is reasonable to assume that many people exposed through their personal care products might also be exposed to 1,4-dioxane residues through cleaners, paints, dyes, or other consumer products. Those same individuals may also be exposed to 1,4-dioxane through drinking water, or may live in a community close to where 1,4-dioxane is processed, manufactured or disposed of. As such, even those "de minimis" exposures from 1,4-dioxane contamination can add up and contribute to an individual's aggregate exposure. Thus, these exposures should be included in the scope of risk evaluations so that EPA can more accurately gauge overall exposure and control risks.

Identifying hazards to "exposed individuals and populations"

EWG encourages EPA to keep in mind that the appropriate processes and procedures to identify susceptible and highly exposed populations may be unique to each substance evaluated. For example, legacy uses of a substance may have disproportionately contaminated particular communities, or exposure to a substance may pose unique health risks for fetal or childhood development. Consequently, EWG urges the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. EWG also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment.[27]

When EPA identifies "any potentially exposed or susceptible subpopulations" and "the hazards to health and the environment that EPA plans to evaluate," the agency should conduct outreach to communities likely to be home to potentially exposed or susceptible subpopulations. These communities may possess crucial information about hazards that the agency may itself lack. For

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[25] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 21 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf ("The extent that manufacturers or processors apply controls or processes to minimize or remove 1,4-dioxane in surfactants during manufacture or before formulation in consumer products is unknown and likely varies by sector.")

[26] *Id.*("manufacturers can apply controls to minimize the formation of 1,4-dioxane or remove most of the 1,4-dioxane present in these products through a vacuum stripping process").

[27] Envtl. Protection Agency, EJ 2020 Action Agenda: EPA's Environmental Justice Strategy, https://www.epa.gov/environmentaljustice/ej-2020-action-agenda-epas-environmental-justice-strategy (last visited Sept. 19, 2017).

example, as highlighted in the comments submitted by Earthjustice et al. in March,[28] such communities are in the best position to inform EPA about nursing homes or schools located near sites that increase the likelihood of their exposures to the chemical. Additionally, workers may be best able to identify real-world occupational exposures to chemicals, including roles and responsibilities that create highly exposed subgroups within their ranks. Other federal, state, and local regulatory authorities may also possess information necessary to establishing the proper scope of a risk assessment. For example, the California EPA has developed child-specific risk values for certain chemicals like atrazine and chlorpyrifos. Those values compare children's susceptibility to adults' by specifically examining child-specific routes of exposure.[29] EPA should review California EPA's approach and adopt its risk values as appropriate, and incorporate information from the analysis California EPA has already completed.

Aggregate and cumulative exposures

As part of a risk assessment, EPA is required to describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered.[30] As emphasized in the above sections, EWG strongly believes that considering the *aggregate* exposures will provide a more robust analysis of the total risk a chemical poses, and that EPA's scoping documents should reflect consideration of those aggregate exposures.

To properly assess aggregate exposures, EPA must consider exposures throughout the lifecycle of the chemical from all routes and pathways, including exposures from conditions of use not regulated by TSCA. This includes exposures from food, drinking water, pesticides, and personal care products, even if those uses are not specifically regulated during section 6(a) rulemaking. EWG emphasizes that this approach should include aggregate exposures from trace contaminants, such as asbestos fibers sometimes found in talc products,[31] or 1,4-dioxane in cleaning and personal care products that contain ethoxylated ingredients.[32]

When possible, EPA should also consider cumulative exposures when scoping a risk evaluation. EPA has explicit authority to order testing and prescribe protocols and methodologies for a number of health and environmental effects – including "cumulative or synergistic effects."[33] Considering cumulative exposures is in line with EPA's priorities and consistent with the best practices for risk evaluations. In *Framework for Cumulative Risk Assessment* (2003), EPA states,

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[28] Alaska Community Action on Toxics, et al., Comments on Scope of the Risk Evaluations for the First Ten Chemicals Under the Toxic Substances Control Act (Mar. 15, 2017).
[29] Cal. EPA, Office of Envtl. Health Hazard Assessment, Child-Specific Reference Doses Finalized to Date, http://oehha.ca.gov/risk-assessment/chrd/table-all-chrds (Jun. 22, 2010).
[30] 15 U.S.C. § 2605(b)(4)(F)(ii).
[31] Ronald Gordon, et. al., Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women, 20 Int'l J. of Occupational and Envt'l Health 318 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164883.
[32] Agency for Toxic Substances & Disease Registry, Public Health Statement for 1,4-Dioxane, Toxic Substances Portal (April 2012), https://www.atsdr.cdc.gov/phs/phs.asp?id=953&tid=199.
[33] 15 U.S.C. § 2603(b)(2)(A).

"Assessing cumulative risk through complex exposures is one of the Agency's high priorities…and it is germane and of great interest to all program and regional offices."[34]

Considering cumulative exposures is important because people and vulnerable subpopulations can be exposed to multiple chemicals and stressors that contribute to the same adverse health effects. The National Academy of Sciences (NAS) has noted the need to evaluate the cumulative effects of phthalates and also pointed to the fact that lead and mercury can collectively affect brain development.[35] Additionally, cumulative exposures to multiple carcinogenic solvents (TCE, 1,4-dioxane, methylene chloride and perchloroethylene) via air and drinking water may pose unique risks for people living near sites with industrial contamination. Taking such cumulative impacts into consideration would improve current assessments, and to the extent possible should be included in scoping.

EPA may consider collective exposure to groups of similar chemicals, and use the Adverse Outcome Pathway framework and database[36] to identify where cumulative effects may be an issue. EPA should follow the cumulative risk assessment process recommended by the National Academy of Sciences (NAS) in their Phthalates and Cumulative Risk Report.[37] When specific information is not available, EPA may use default values to account for cumulative exposures.

Conclusion

EWG appreciates the opportunity to comment on the scoping documents for the first 10 TSCA substances. We hope that these comments will help EPA to reevaluate the scoping documents of the first 10 TSCA substances so that they address fully the ways in which vulnerable and chemically over-burdened populations around the country are placed at risk by these chemicals. We look forward to continuing to participate in EPA's risk evaluation and risk management efforts under TSCA. Should you have any additional questions, please feel free to reach out to Melanie Benesh, Legislative Attorney at EWG, 202-939-0120, mbenesh@ewg.org.

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[34] Envtl. Protection Agency, Framework for Cumulative Risk Assessment, p. xi https://www.epa.gov/sites/production/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (last accessed Sept. 19, 2017).

[35] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508.

[36] Adverse Outcome Pathway Knowledge Database, Org. for Econ. Co-Operation & Dev., http://aopkb.org/ (last visited March 20, 2016).

[37] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508..

Document ID	Commenter	Issue / Theme
EPA-HQ-OPPT-2016-0737-0036	Juleen Lam, PhD, Associate Researcher, University of California et al.	Risk evaluation
EPA-HQ-OPPT-2016-0737-0037		
EPA-HQ-OPPT-2016-0737-0038		
EPA-HQ-OPPT-2016-0737-0039		
EPA-HQ-OPPT-2016-0737-0040		
EPA-HQ-OPPT-2016-0737-0041		
EPA-HQ-OPPT-2016-0737-0042		
EPA-HQ-OPPT-2016-0737-0043		
EPA-HQ-OPPT-2016-0737-0044		
EPA-HQ-OPPT-2016-0737-0045		
EPA-HQ-OPPT-2016-0737-0046		
EPA-HQ-OPPT-2016-0737-0047		
EPA-HQ-OPPT-2016-0737-0048		
EPA-HQ-OPPT-2016-0737-0049		

Comment
Incorporate a broad consideration of chemical use profiles that captures current uses in addition to reasonably foreseen applications that consider the full cradle-to-grave chemical lifecycle; Ensure that the chemical evaluations are designed to be fully protective of public health, particularly the health of vulnerable and susceptible populations, and adequately capture real-world scenarios by considering aggregate exposures; Not solely rely on the use of product labels (such as those specifying use of Personal Protection Equipment (PPE)) to guarantee health protection of occupational workers and consumers, as these are inadequate to fully protect public health; Not assume that absence of data means that there is no hazard or risk: these data voids should be identified during scoping and problem formulation activities, and efforts to obtain or generate the required data should be pursued immediately; Encourage and actively seek input from fence-line and other impacted communities, occupational workers at manufacturing, processing, distributing, or recycling facilities, concerned members from the public, and tribal communities and incorporate their concerns in the Agency's evaluations where appropriate.
Memo authorizing the opening of a comment period for this docket.
Stakeholder Meeting with AFL-CIO - March 9, 2017
Stakeholder Meeting with AIA - February 27, 2017
Stakeholder Meeting with APHL - February 28, 2017
Stakeholder Meeting with ARAP - March 8, 2017
Stakeholder Meeting with California State Agencies - January 25, 2017
Stakeholder Meeting with CSPA - January 10, 2017
Stakeholder Meeting with CTA - March 14, 2017
Stakeholder Meeting with CUC - January 26, 2017
Stakeholder Meeting with Earthjustice - February 15, 2017
Stakeholder Meeting with EDF - January 3, 2017
Stakeholder Meeting with EWG - January 17, 2017
Stakeholder Meeting with HSIA - January 9, 2017

EPA-HQ-OPPT-2016-0737-0050		
EPA-HQ-OPPT-2016-0737-0051		
EPA-HQ-OPPT-2016-0737-0052		
EPA-HQ-OPPT-2016-0737-0053	David Crandell, President, Parts Cleaning Technologies, LLC	Risk evaluation
EPA-HQ-OPPT-2016-0737-0054	W. Caffey Norman, Squire Patton Boggs (US) LLP on behalf of Faye Graul, Executive Director, Halogenated Solvents Industry Alliance, Inc. (HSIA)	
EPA-HQ-OPPT-2016-0737-0055		
EPA-HQ-OPPT-2016-0737-0056		
EPA-HQ-OPPT-2016-0737-0057		
EPA-HQ-OPPT-2016-0737-0058	David Crandell, President, Parts Cleaning Technologies, LLC	
EPA-HQ-OPPT-2016-0737-0059		
EPA-HQ-OPPT-2016-0737-0060	Georges C. Benjamin, MD, Executive Director, American Public Health Association (APHA)	

Stakeholder Meeting with IRTA - March 9, 2017
Stakeholder Meeting with NRDC - January 11, 2017
Stakeholder Meeting with Occidental - January 18, 2017
Based on 25 years of actual industry experience , the exposure to TCE in the workplace is significantly less than portrayed in the Dockets. Worker exposure, viable replacement processes and the resultant financial impact of said processes are incorrect and require additional analysis.
Copy of HSIA's comments on EPA's proposed rule banning manufacture of TCE for use in vapor degreasing.
Strategy for Conducting Literature Searches for Trichloroethylene (TCE): Supplemental Document to the TSCA Scope Document
Trichloroethylene Market and Use Report
Scope of the Risk Evaluation for Trichloroethylene
Duplicate of EPA-HQ-OPPT-2016-0737-0053
Trichloroethylene (79-01-6) Bibliography: Supplemental File for the TSCA Scope Document
EPA should assess aggregate exposures within and across populations resulting from all current and legacy uses of a chemical substance to avoid underestimating risk. EPA should conduct hazard identification by following systematic review processes that integrate animal, human, and mechanistic evidence. EPA should follow recommendations from NAS to identify vulnerable subpopulations based on established risk factors that increase susceptibility or exposure. EPA should use health-protective defaults if the agency lacks information specific to a chemical, and health-protective methods to quantify risk when characterizing risk. EPA should require that claims of confidential business information be fully substantiated by industry and not used to conceal critical information from the public.

EPA-HQ-OPPT-2016-0737-0061	Lynne Haber, PhD, Senior Toxicologist/Adjunct Associate Professor, Department of Environmental Health, University of Cincinnati, College of Medicine	Risk evaluation
EPA-HQ-OPPT-2016-0737-0062	OASD (EI&E), ESOH Directorate, CMRM Program, Department of Defense (DOD)	Risk evaluation

Shared results of a multi-stakeholder project relevant to improving risk assessment methods and practice, that can be a useful resource for your work. The Alliance for Risk Assessment (ARA) project "Beyond 'Science & Decisions' from Problem Formulation to Dose-Response Assessment" has extended the work begun by the 2009 NRC report "Science and Decisions: Advancing Risk Assessment" by broadening and deepening scientific discussion on two key recommendations: improving problem formulation and selecting appropriate dose-response assessment methodology.

Ex. 5 Deliberative Process (DP)

EPA-HQ-OPPT-2016-0737-0063	Faye Graul, Executive Director, Halogenated Solvents Industry Alliance, Inc. (HSIA)	Risk evaluation
EPA-HQ-OPPT-2016-0737-0064	Sarah E. Amick, Vice President, EHS&S, Senior Counsel, U .S. Tire Manufacturers Association (USTMA)	Risk evaluation
EPA-HQ-OPPT-2016-0737-0065	Stephen P. Risotto, Senior Director, Chemical Products and Technology Division, American Chemistry Council (ACC)	Risk evaluation

HSIA would strongly recommend that, in development of the problem formulation documents for the four chlorinated organics, EPA give serious consideration to its own guidance document Framework for Human Health Risk Assessment to Inform Decision Making. Further broadening of EPA's mandate under TSCA for chemicals that are already subjected to extensive regulation presents serious conflicts both in assessing potential human health and environmental risks and in any subsequent risk management decisions. EPA should use discretion in its selection of conditions of use. EPA should exclude certain de minimis conditions of use. Given our understanding of the use of these solvents as intermediates, HSIA believes there is a sufficient basis to exclude this "condition of use" from further consideration in the risk evaluation. EPA should consider a tiered approach to address de minimis and/or heavily regulated exposures. Legacy sources of exposure should not be addressed under LCSA. Protection from workplace exposures to chemicals is the primary responsibility of OSHA, not EPA. Risk evaluations conducted under LCSA should be state-of-the-art. EPA's approach for evaluating environmental impacts under LCSA is problematic.
TCE is not used by USTMA member companies in the process of manufacturing tires or the process of producing retreaded tires. However, TCE may be an ingredient in materials in tire repair cement and/or sealers at facilities that repair tires.
Existing health assessments of TCE conducted by the Environmental Protection Agency (EPA) – including the 2011 Integrated Risk Information System (IRIS) assessment conducted by the National Center for Environmental Assessment (NCEA) and OPPT's own 2014 assessment under the Work Plan Chemicals program – do not comply with the requirements for the use of the best available science and weight of scientific evidence (WOE) as required by TSCA §26(i) and as defined in the Agency's risk evaluation procedures. In particular, the previous EPA assessments fail to consider the weight of evidence when evaluating the reported association between TCE exposure and fetal heart malformations (FHM). In evaluating the potential developmental toxicity of TCE under TSCA, OPPT will be required to conduct an independent, systematic review of the available information for FHM as outlined in the risk evaluation rule.

EPA-HQ-OPPT-2016-0737-0066	Veena Singla, PhD, Juleen Lam, PhD and Tracey Woodruff, PhD, UCSF Program on Reproductive Health and the Environment on behalf of Green Barn Research et al.	Risk evaluation
EPA-HQ-OPPT-2016-0737-0067	Miles Free, Director, Industry Research and Technology, Precision Machined Products Association (PMPA)	Risk evaluation
EPA-HQ-OPPT-2016-0737-0068	Jessica Helm, PhD and Kathryn Rodgers, MPH, Silent Spring Institute	
EPA-HQ-OPPT-2016-0737-0069	Mark S. Rossi, PhD, Executive Director, Clean Production Action	

EPA should improve its literature search and systematic review strategies to strengthen its evaluations and increase transparency. EPA needs to consider aggregate exposure within and across populations; otherwise it will underestimate risk. Aggregate exposure should include legacy uses, uses where a chemical is present as a contaminant or by-product, and uses already assessed by EPA. EPA appropriately identifies factors to consider to identify populations subject to greater exposures. EPA should also address susceptible sub-populations, following recommendations from the National Academies of Sciences (NAS) to identify susceptible sub-populations based on established extrinsic and intrinsic factors that increase vulnerability. EPA should rely on existing IRIS assessments for hazard identification. Moving forward, EPA should complete hazard identification or add additional studies only through a systematic review process, which integrates animal, human and mechanistic evidence as recommended by the recent NAS report. For risk characterization, EPA should use defaults and methods that account for the full range of risks in the population and that will form the basis of decisions that protect the public's health. Confidential Business Information (CBI) claims should not be used to obscure critical data and information from the public.
Copy of comments submitted during comment period of rulemaking on TCE for use in vapor degreasing. Comprised of over 440 members, we are concerned that a broad formulation could have a chilling effect on small and medium downstream manufacturers, causing business closures and sector layoffs.
In order to ensure that exposure models and assessments adequately capture exposure, we encourage EPA to consider aggregate exposures. It is essential for EPA to include exposures from uses already assessed in aggregate exposure assessment. We would like EPA to clarify how it plans to use sentinel exposure assessment in future scoping documents. We encourage EPA to consider the maximum or 99th percentile when calculating the risk. Pertaining to EPA's decision to conduct an assessment of cancer hazard from TCE, we encourage EPA to specifically consider mammary tumors as an endpoint. Because exposure to TCE co-occurs with other related chemicals, cumulative effects from co-exposures to chemicals that act in similar ways should be considered. Risk to susceptible populations should be included.
The BizNGO Chemical Alternatives Assessment Protocol is a decision framework that promotes innovation for safer chemicals. It gives companies a process for identifying alternatives to a chemical of concern, screening out alternatives of equal or greater hazard, and selecting a safer alternative that is technically and economically viable. The Protocol is both descriptive—describes best business practice—and normative—describes how businesses should evaluate and select safer alternatives. Thus it is a recommended decision framework from BizNGO based on business practice.

EPA-HQ-OPPT-2016-0737-0070	Robert Stockman, Senior Attorney, Environmental Defense Fund (EDF)	

These scopes deviate from certain requirements of the law and in places are too unclear and vague or ambiguous to allow us to provide definitive comments. EDF recognizes that EPA was working under tight deadlines in producing these scopes – a problem it further exacerbated by EPA's decision to make major, late changes to the risk evaluation rule. EPA should take advantage of the upcoming problem formulation stage to address the many problems we identify below, and to more clearly and transparently explain its plans for these risk evaluations. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use. EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA §§ 4 and 8 to obtain additional information. EPA needs to take additional steps to ensure both the completeness and accuracy of the information it relies upon. These scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures. DCM, and NMP is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses. In the scope for TCE, EPA suggests that TCE's use as a spot remover will not be analyzed because it was previously analyzed in a risk evaluation; that approach may be reasonable if EPA finalizes its proposed ban on this use of TCE to address those risks; but that approach only applies to those spot remover uses that have previously been analyzed, specifically commercial dry cleaning facilities; this risk evaluation needs to consider TCE's use as a consumer spot remover; those uses have not been analyzed in-depth, and the 2014 work plan assessment recognized that some such products may contain TCE as a main ingredient.

EPA-HQ-OPPT-2016-0737-0071	Elizabeth Hitchcock, Government Affairs Director, Safer Chemicals Healthy Families (SCHF) et al.	
EPA-HQ-OPPT-2016-0737-0072	Environmental Working Group (EWG)	

Problem formulation can fill gaps in scoping documents and enhance their depth of analysis but cannot be used to remove uses, exposures and hazards from the risk evaluation scope. EPA should use problem formulation to provide more detail on the potentially exposed and susceptible subpopulations it will consider and how risks to these subpopulations will be determined. Problem formulations should also describe EPA's strategies for assessing risks from aggregate and cumulative exposures. Ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations. Chemicals with ozone depletion and global warming potential pose environmental and health risks that fall within the scope of TSCA risk evaluations. EPA risk evaluations should not reassess uses of trichloroethylene (TCE) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals. In the course of TSCA risk evaluations, EPA should not revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address. In evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective. In order to apply these general principles and fill other gaps in its scoping documents, these documents must be expanded and strengthened in several specific respects during problem formulation. EPA should not prejudge the absence of adverse effects for particular end-points at the scoping stage but should defer such conclusions until the systematic review phase of its risk evaluation as the law requires. Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties. EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired.
EPA's scoping documents on the first 10 chemicals should be revised as needed to ensure they include: reasonably foreseeable uses like accidents, misuses, and off-label uses; the entire lifecycle of the chemical; exposures from non-TSCA uses; contaminants and low-concentration uses that contribute to overall exposure; exposures for which data is limited; risks to potentially exposed and susceptible populations; risks from aggregate and cumulative exposures.

EPA-HQ-OPPT-2016-0737-0073	Jennifer Sass, PhD, Senior Scientist, Natural Resources Defense Council (NRDC)	
EPA-HQ-OPPT-2016-0737-0074	Toxics Use Reduction Institute (TURI)	
EPA-HQ-OPPT-2016-0737-0075	Halogenated Solvents Industry Alliance, Inc. (HSIA)	Risk evaluation

Effective use of Personal Protective Equipment (PPC) should not be presumed. Limitations and weaknesses of alternative testing methods should be considered. Previous findings on hazard and risk from the IRIS assessments should be presumed valid and incorporated in risk evaluations. All conditions of use must be included and addressed under TSCA. EPA failed to include exposures from non-TSCA uses such as food and food contact materials and should include them. NRDC supports EPA's statement that it will include workers and occupational non-users, consumers, bystanders and other groups and individuals that experience greater exposures and therefore greater health risks than the general population. NRDC also supports EPA's statement that it will include exposures to the general population and the environment via inhalation of contaminated air. NRDC supports EPA's statement that it will use existing TSCA risk assessments to inform its development of the TCE risk evaluation. NRDC supports EPA's statement that it will include all adverse effects associated with TCE, including reproductive and developmental toxicity, including the risks from exposures in both men and women. NRDC also appreciates that EPA included vapor intrusion. All product uses and exposure routes must always be included if they are circumstances under which the chemical "is intended, known, or reasonably foreseen" to be distributed or used. It is unlawful for EPA to not consider product uses and exposure routes. Instead, during problem formulation, EPA should provide more detail on the uses, exposures and environmental releases relevant to vapor and mists, and EPA should clarify how they will be analyzed during risk evaluations.
Need to consider all uses; importance of worker exposures and susceptible subpopulations; and consideration of information available through TURA.
Copy of HSIA's comments on EPA's proposed rule banning manufacture of TCE for use in aerosol degreasing and use as a spotting agent in dry cleaning. Protocol of Oral (Drinking Water) Study of the Effects of Trichloroethylene (TCE) on Fetal Heart Development in Sprague Dawley Rats. Comments on the Weight of Evidence Cancer Conclusions in the Trichloroethylene: Consideration of Both Toxicological and Epidemiologic Evidence - External Review Draft.

September 19, 2017

EWG Comments on the Risk Evaluation Scoping for the First 10 Chemicals Under TSCA

Docket ID Nos.: EPA-HQ-OPPT-2016-0723 (1,4- Dioxane); EPA-HQ-OPPT-2016-0725 (Pigment Violent 29) EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene (also known as perchloroethylene)); EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride); EPA-HQ-OPPT-2016-0735 (Cyclic Aliphatic Bromide Cluster (HBCD)); EPA-HQ-OPPT-2016-0736 (Asbestos); EPA-HQ-OPPT-2016-0737 (Trichloroethylene (TCE)); EPA-HQ-OPPT-2016-0741 (1-Bromopropane); EPA-HQ-OPPT-2016-0742 (Methylene Chloride); and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone (NMP)).

The Environmental Working Group (EWG) is a nonprofit advocacy organization dedicated to improving environmental health. EWG has long advocated for stronger federal chemical regulations and spent over a decade advocating for reforms to strengthen the Toxic Substances Control Act (TSCA). The Frank R. Lautenberg Chemical Safety for the 21st Century Act (hereinafter "Lautenberg Act") for the first time will require the Environmental Protection Agency (EPA) to comprehensively review existing chemicals on the TSCA inventory—starting with 10 work plan chemicals, as required by section 6(b)(2)(A).[1] As the first chemicals assessed under the recently overhauled law, these first 10 assessments represent an early test of the strength of the new law. As such, it is important that the scopes of these first 10 chemical risk evaluations adequately consider the diverse uses of each chemical and the unique ways that vulnerable and chemically over-burdened populations may be at risk.

We submit these comments generally to apply to all 10 scoping documents released by EPA on June 22, 2017. The following comments are meant to assist EPA to strengthen the proposed scopes of the first 10 chemicals before it moves into the problem formulation phase of the risk evaluation process. In particular, EWG comments that EPA's scoping documents on the first 10 chemicals should be revised as needed to ensure they include:

- Reasonably foreseeable uses like accidents, misuses, and off-label uses
- The entire lifecycle of the chemical
- Exposures from non-TSCA uses
- Contaminants and low-concentration uses that contribute to overall exposure
- Exposures for which data is limited
- Risks to potentially exposed and susceptible populations
- Risks from aggregate and cumulative exposures

Accidents, misuses, and off-label uses

[1] 15 U.S.C. § 2605(b)(2)(A).

Pursuant to TSCA section 6(b)(4)(D), a chemical's scoping document should include "the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider."[2]

The Lautenberg Act defined "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[3] The plain language of this definition requires EPA to consider not only the intended and known uses of a chemical, but also any "reasonably foreseeable uses."

Reasonably foreseeable uses should include accidents like chemical spills and leaks that can contaminate air, water, and soil. The National Environmental Policy Act ("NEPA") highlights how "reasonable foreseeability" includes accidental releases in the context of environmental law. NEPA requires federal agencies to prepare an environmental impact statement ("EIS") for any proposed major federal action "significantly affecting the quality of the human environment."[4]

Other language in TSCA further underscores the intention to include accidental or inadvertent releases or exposures. The process for prioritizing chemicals requires EPA to consider "storage near significant sources of drinking water."[5] This is a clear reference to potential risks from accidental spills or leaks, or even criminal releases, into drinking water.

EWG is further concerned by EPA's stated intent to generally exclude "intentional misuses" from the scope of a chemical risk evaluation.[6] Reasonably foreseeable uses would also include foreseeable misuses, whether they are intentional or not. For example, a consumer may foreseeably misuse cleaning and other consumer products in several ways. A bathtub cleaner may also be used to clean the bathroom sink. A cleaner that is meant to be sprayed from 8 to 10 inches away may instead be sprayed from 3 inches away. Consumers and workers may apply more or less of a product than what is directed. Chemical facilities may intentionally improperly release or dispose of a chemical. These misuses are reasonably foreseeable and should be included in the scope of a risk evaluation.

Lifecycle of chemical, including legacy uses

Section 6(a) requires EPA to regulate when an unreasonable risk is posed by the "manufacture, processing, distribution in commerce, use, or disposal" of a chemical or "any combination such activities."[7] This makes clear that in the scope of a risk assessment, EPA must account for the entire lifecycle of the chemical, including risks during production, processing, distribution, recycling, and disposal, or any combination of those activities. It follows that the scope of EPA's risk evaluations should include both current and also legacy uses, as well as legacy disposal. As

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[2] 15 U.S.C. 2605 (b)(4)(D).
[3] 15 U.S.C. 2602(4).
[4] 42 U.S.C. § 4332(2)(C)(i).
[5] 15 U.S.C. § 2605(b)(1)(A).
[6] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).
[7] 15 U.S.C. 2605(a).

such, EWG is concerned by EPA's stated intention to focus on "uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal."[8]

This interpretation undermines the design of TSCA as a cradle-to-grave statute and is at odds with EPA's clear mandate to evaluate and regulate risks at the end of a chemical's lifecycle. Excluding legacy uses is also at odds with EPA's requirement to "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance."[9] To fully consider the frequency and number of exposures to a chemical, EPA must consider likely exposure from all sources—regardless of whether the exposure came from an ongoing or a legacy use.

Asbestos and the HBCD provide important examples. Both chemicals may be found in previously installed insulation and other building materials in homes, offices, schools and other buildings. They can be released if disturbed, creating an exposure risk. Thousands of American homes have asbestos-containing vermiculite insulation, and millions have HBCD-containing insulation board. As insulation ages, chemicals like HBCD and asbestos can migrate into household dust.

Building materials may also be improperly removed or disposed of, creating additional exposure risks. For example, in 2016, the Washington State Attorney General brought charges against a hotel owner for improper asbestos removal.[10] According to the news release, the owner lied about the extent of renovations in order to get around asbestos surveying and permit requirements. As a result, workers, inspectors, and people living near the hotel were all potentially exposed to unsafe levels of asbestos from legacy uses.

The prevalence of these legacy uses underscores the importance of including them in risk evaluations. Without considering exposure from legacy uses or disposal, EPA will be unable to assess the aggregate exposure because it will not have a complete picture of the "likely duration, intensity, frequency, and number of exposures to a chemical."

Consideration of non-TSCA uses

The requirement that EPA consider the "hazards, exposures, [and] conditions of use" in its scoping documents and also the "likely duration, intensity, frequency, and number of exposures" means that EPA must also consider uses covered by other agencies and statutes.

EWG is concerned by EPA's assertion that "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly

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[8] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017).
[9] 15 U.S.C. § 2605(b)(4)(F)(iv).
[10] Press Release, Washington State Office of the Attorney General, AG Files Criminal Charges Against Hotel Owner over Asbestos Removal (May 11, 2016), http://www.atg.wa.gov/news/news-releases/ag-files-criminal-charges-against-hotel-owner-over-asbestos-removal.

where the other agency has effectively managed the risks."[11] Even if another agency has taken steps to manage risk from a particular use, that doesn't mean the use does not contribute to exposure or that the risk has been eliminated. For example, many of the first 10 chemicals pose occupational risks that may be regulated by OSHA. However, oftentimes OSHA's regulations need to be updated or do not go far enough. For example, OSHA has a permissible exposure limit (PEL) for trichloroethylene, or TCE, but it is already 20 years old.[12] Additionally, even OSHA admits that many of its PELs are outdated and do not adequately protect workers from chemicals.[13] As such, action taken by OSHA should not be a basis for excluding occupational uses from a risk evaluation scope.

Likewise, several TSCA-regulated chemicals also have FDA-regulated uses. Although methylene chloride is primarily used as a paint stripper and remover,[14] FDA has also approved it as a food additive for uses including as a solvent in the extraction of caffeine from green coffee beans.[15] A person who uses a methylene chloride-based paint stripper may also drink decaffeinated coffee and could be exposed from both sources. 1,4-Dioxane, used industrially as a solvent and chemical stabilizer, is a well-known contaminant in personal care and other consumer products. A recent analysis by EWG found that as many as 8,000 personal care products contain ethoxylated ingredients manufactured through a process that may create 1,4-dioxane as a byproduct.[16] An individual exposed to 1,4-dioxane in an occupational setting would likely also be exposed to 1,4-dioxane through their personal care or cleaning products.

Finally, non-TSCA uses include uses regulated by EPA, but under other statutes. Several of the first 10 chemicals—including 1,4-dioxane, TCE, tetrachlorethylene (perc), methylene chloride, asbestos, and carbon tetrachloride—are known to contaminate drinking water systems, according to nationwide water testing results analyzed in EWG's recently released Tap Water Database.[17] These chemicals are detected in concentrations that exceed health guidelines in drinking water served to millions of Americans, sometimes in combination with each other due to a common industrial source. Of these contaminants, EPA has yet to set an enforceable drinking water standard for 1,4-dioxane. The Maximum Contaminant Levels set for carbon tetrachloride, TCE, tetrachlorethylene, and methylene chloride are all less health-protective than other standards or public health goals promulgated by EPA or other public health agencies such as the California Office of Environmental Health Hazard Assessment. Even so, EWG's analysis found drinking water violations in some drinking water systems that had levels of carbon tetrachloride, TCE,

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[11] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).

[12] Envtl. Protection Agency, Scope of the Risk Evaluation for Trichloroethylene, p. 32 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf

[13] U.S. Dep't of Labor, Occupational Safety and Health Administration, Permissible Exposure Limits—Annotated Tables, https://www.osha.gov/dsg/annotated-pels/ (last accessed Sept. 19, 2017).

[14] ATSDR, Toxicological Profile for Methylene Chloride, pp. 1-2, https://www.atsdr.cdc.gov/toxprofiles/tp14.pdf (last accessed March 7, 2017).

[15] 21 C.F.R. § 173.255(c).

[16] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

[17] Envtl. Working Grp., EWG's Tap Water Database, All Contaminants, https://www.ewg.org/tapwater/chemical-contaminants.php#.WcCifNN96CQ.

and tetrachlorethylene exceeding the MCLs. Because water contamination is so pervasive, and EPA's enforceable drinking water standards are often not sufficiently protective, EPA should always consider exposure from drinking water as part of its risk assessments.

These examples show that people are exposed to chemicals in myriad ways that often fall under the jurisdiction of different laws and different agencies. While EPA would only regulate some of those uses under TSCA, uses and exposures that occur outside of TSCA's jurisdiction contribute to an individual's aggregate exposure, and thus could contribute to an unreasonable risk of injury to health and must be considered.

Must be based on adequate information

EPA should not omit a condition of use from the scope of the risk assessment because data on that particular use is lacking. For example, EPA has insufficient information about the likely exposure of workers and people living in homes that use HBCD insulation. EPA also has limited information about 1,4-dioxane levels in products that contain ethoxylated ingredients. EPA should study exposures rather than make assumptions based on the limited data. After all, the law requires EPA to actively seek "reasonably available information" about conditions of use from stakeholders.[18]

"Reasonably available" is defined broadly in the final risk evaluation rule to include not only information EPA possesses, but also all information EPA can "reasonably generate, obtain, and synthesize for use in risk evaluations."[19] This would include information published in scientific journals and industry studies. It would also include information already collected by state governments or under foreign regulations like the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) in Europe. If EPA knows this information exists and was submitted to other governments, it should take measures to request the same information from the manufacturers or processors responsible for its submission. Additionally, EWG encourages EPA to rely on the appropriate use of defaults, or calculated uncertainty factors when specific information is missing. Finally, EPA has various tools under sections 4, 8(a), 8(c), 11 and 26(a) to order testing or solicit information as needed to fill data gaps.

Exposure from contaminants or impurities

EWG is concerned by EPA's stated intent to generally exclude impurities and other "de minimis" exposures from the scope of its risk evaluations.[20]

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[18] 15 U.S.C. § 2625(k) ("The Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator."); 15 § 2605(b)(4)(F)(i).

[19] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33748 (July 20, 2017) (to be codified at 40 C.F.R. pt. 702.33).

[20] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017)("EPA may choose not to include a particular impurity within the Scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the impurity would be 'de minimis' or otherwise insignificant.")

This general exclusion falsely equates de minimis exposures with low risk. It disregards the significant body of evidence that hormone disruptors and developmental toxicants may cause adverse effects at very low doses, and ignores the possibility of nonmonotonic dose-response curves. The pharmaceutical literature is rife with examples of nonmonotonicity, timing and age-group specific toxicity concerns.[21] Furthermore, even de minimis exposures contribute to an individual's aggregate exposure to a chemical.

An important example is 1,4-dioxane. 1,4-Dioxane is a well-known impurity that occurs as a byproduct of the ethoxylation process. In the scoping document for 1,4-dioxane, EPA has indicated it will exclude these uses from the scope of its evaluation. Specifically, EPA states that:

> In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane.[22]

This approach is backwards. 1,4-Dioxane is a likely carcinogen and is associated with several other health effects, including liver and kidney damage, lung irritation, and eye, nose, and throat irritation.[23] Whether the presence of 1,4-dioxane in a product is intentional or the result of contamination does not change the potential health risks. Furthermore, it makes more sense to examine the risks from 1,4-dioxane formation in the context of the risk evaluation on 1,4-dioxane when EPA will be looking at other routes of 1,4-dioxane exposure and specifically analyzing the risks from 1,4-dioxane.

Several chemicals form 1,4-dioxane as part of the ethoxylation process. An analysis of EWG's Skin Deep database found that as many as 8,000 products contained ethoxylated ingredients that create 1,4-dioxane as a byproduct during manufacturing.[24] Presumably, future EPA risk evaluations on any of those ethoxylated chemicals will be focused on the risks posed by those chemicals themselves, with 1,4-dioxane formation considered only as a secondary issue. Furthermore, evaluating 1,4-dioxane formation as part of the risk evaluation for each ethoxylated chemical separately—each of which could be years or decades apart—would give EPA a disjointed and incomplete picture of the real problem.

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[21] See, e.g., Non-monotonic Dose Response Curves, Our Stolen Future, http://www.ourstolenfuture.org/NewScience/lowdose/nonmonotonic.htm (last visited Sept. 19, 2017).
[22] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 8 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf (emphasis added).
[23] ATSDR, Toxicological Profile for 1,4-dioxane, Relevance to Public Health, p. 2, https://www.atsdr.cdc.gov/toxprofiles/tp187-c2.pdf (last accessed Sept. 19, 2017).
[24] Press Release, Envtl. Working Grp., EWG Surveys Personal Care Companies About 1,4-Dioxane (April 17, 2017), http://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane#.WcCe2tN96CQ.

As EPA admits,[25] there is little information about how widespread contamination from 1,4-dioxane is in consumer products with ethoxylated ingredients. Because it's not intentionally added it does not need to be listed on product labels, and companies are not required to measure or disclose levels of 1,4-dioxane in their products. As such, there is little way to know if 1,4-dioxane is present and, if so, at what levels. While manufacturers can take steps to minimize 1,4-dioxane formation or vacuum strip it from products, manufacturers are also not required to report if they are doing so.[26] EPA should not make assumptions based on what it does not know, but should instead study the issue.

Without more information, EPA cannot assume that 1,4-dioxane exposures through personal care and other consumer products are minimal and not a concern. Americans use several different kinds of personal care products every day, many of which contain ethoxylated ingredients and could be contaminated with 1,4-dioxane. It is reasonable to assume that many people exposed through their personal care products might also be exposed to 1,4-dioxane residues through cleaners, paints, dyes, or other consumer products. Those same individuals may also be exposed to 1,4-dioxane through drinking water, or may live in a community close to where 1,4-dioxane is processed, manufactured or disposed of. As such, even those "de minimis" exposures from 1,4-dioxane contamination can add up and contribute to an individual's aggregate exposure. Thus, these exposures should be included in the scope of risk evaluations so that EPA can more accurately gauge overall exposure and control risks.

Identifying hazards to "exposed individuals and populations"

EWG encourages EPA to keep in mind that the appropriate processes and procedures to identify susceptible and highly exposed populations may be unique to each substance evaluated. For example, legacy uses of a substance may have disproportionately contaminated particular communities, or exposure to a substance may pose unique health risks for fetal or childhood development. Consequently, EWG urges the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. EWG also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment.[27]

When EPA identifies "any potentially exposed or susceptible subpopulations" and "the hazards to health and the environment that EPA plans to evaluate," the agency should conduct outreach to communities likely to be home to potentially exposed or susceptible subpopulations. These communities may possess crucial information about hazards that the agency may itself lack. For

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[25] Envtl. Protection Agency, Scope of the Risk Evaluation for 1,4-Dioxane, p. 21 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf ("The extent that manufacturers or processors apply controls or processes to minimize or remove 1,4-dioxane in surfactants during manufacture or before formulation in consumer products is unknown and likely varies by sector.")

[26] *Id.*("manufacturers can apply controls to minimize the formation of 1,4-dioxane or remove most of the 1,4-dioxane present in these products through a vacuum stripping process").

[27] Envtl. Protection Agency, EJ 2020 Action Agenda: EPA's Environmental Justice Strategy, https://www.epa.gov/environmentaljustice/ej-2020-action-agenda-epas-environmental-justice-strategy (last visited Sept. 19, 2017).

example, as highlighted in the comments submitted by Earthjustice et al. in March,[28] such communities are in the best position to inform EPA about nursing homes or schools located near sites that increase the likelihood of their exposures to the chemical. Additionally, workers may be best able to identify real-world occupational exposures to chemicals, including roles and responsibilities that create highly exposed subgroups within their ranks. Other federal, state, and local regulatory authorities may also possess information necessary to establishing the proper scope of a risk assessment. For example, the California EPA has developed child-specific risk values for certain chemicals like atrazine and chlorpyrifos. Those values compare children's susceptibility to adults' by specifically examining child-specific routes of exposure.[29] EPA should review California EPA's approach and adopt its risk values as appropriate, and incorporate information from the analysis California EPA has already completed.

Aggregate and cumulative exposures

As part of a risk assessment, EPA is required to describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered.[30] As emphasized in the above sections, EWG strongly believes that considering the *aggregate* exposures will provide a more robust analysis of the total risk a chemical poses, and that EPA's scoping documents should reflect consideration of those aggregate exposures.

To properly assess aggregate exposures, EPA must consider exposures throughout the lifecycle of the chemical from all routes and pathways, including exposures from conditions of use not regulated by TSCA. This includes exposures from food, drinking water, pesticides, and personal care products, even if those uses are not specifically regulated during section 6(a) rulemaking. EWG emphasizes that this approach should include aggregate exposures from trace contaminants, such as asbestos fibers sometimes found in talc products,[31] or 1,4-dioxane in cleaning and personal care products that contain ethoxylated ingredients.[32]

When possible, EPA should also consider cumulative exposures when scoping a risk evaluation. EPA has explicit authority to order testing and prescribe protocols and methodologies for a number of health and environmental effects – including "cumulative or synergistic effects."[33] Considering cumulative exposures is in line with EPA's priorities and consistent with the best practices for risk evaluations. In *Framework for Cumulative Risk Assessment* (2003), EPA states,

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[28] Alaska Community Action on Toxics, et al., Comments on Scope of the Risk Evaluations for the First Ten Chemicals Under the Toxic Substances Control Act (Mar. 15, 2017).
[29] Cal. EPA, Office of Envtl. Health Hazard Assessment, Child-Specific Reference Doses Finalized to Date, http://oehha.ca.gov/risk-assessment/chrd/table-all-chrds (Jun. 22, 2010).
[30] 15 U.S.C. § 2605(b)(4)(F)(ii).
[31] Ronald Gordon, et. al., Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women, 20 Int'l J. of Occupational and Envt'l Health 318 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164883.
[32] Agency for Toxic Substances & Disease Registry, Public Health Statement for 1,4-Dioxane, Toxic Substances Portal (April 2012), https://www.atsdr.cdc.gov/phs/phs.asp?id=953&tid=199.
[33] 15 U.S.C. § 2603(b)(2)(A).

"Assessing cumulative risk through complex exposures is one of the Agency's high priorities…and it is germane and of great interest to all program and regional offices."[34]

Considering cumulative exposures is important because people and vulnerable subpopulations can be exposed to multiple chemicals and stressors that contribute to the same adverse health effects. The National Academy of Sciences (NAS) has noted the need to evaluate the cumulative effects of phthalates and also pointed to the fact that lead and mercury can collectively affect brain development.[35] Additionally, cumulative exposures to multiple carcinogenic solvents (TCE, 1,4-dioxane, methylene chloride and perchloroethylene) via air and drinking water may pose unique risks for people living near sites with industrial contamination. Taking such cumulative impacts into consideration would improve current assessments, and to the extent possible should be included in scoping.

EPA may consider collective exposure to groups of similar chemicals, and use the Adverse Outcome Pathway framework and database[36] to identify where cumulative effects may be an issue. EPA should follow the cumulative risk assessment process recommended by the National Academy of Sciences (NAS) in their Phthalates and Cumulative Risk Report.[37] When specific information is not available, EPA may use default values to account for cumulative exposures.

Conclusion

EWG appreciates the opportunity to comment on the scoping documents for the first 10 TSCA substances. We hope that these comments will help EPA to reevaluate the scoping documents of the first 10 TSCA substances so that they address fully the ways in which vulnerable and chemically over-burdened populations around the country are placed at risk by these chemicals. We look forward to continuing to participate in EPA's risk evaluation and risk management efforts under TSCA. Should you have any additional questions, please feel free to reach out to Melanie Benesh, Legislative Attorney at EWG, 202-939-0120, mbenesh@ewg.org.

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[34] Envtl. Protection Agency, Framework for Cumulative Risk Assessment, p. xi https://www.epa.gov/sites/production/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (last accessed Sept. 19, 2017).

[35] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508.

[36] Adverse Outcome Pathway Knowledge Database, Org. for Econ. Co-Operation & Dev., http://aopkb.org/ (last visited March 20, 2016).

[37] Nat'l Acad. Sci., Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508..

HSIA
halogenated solvents industry alliance, inc.

September 19, 2017

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: Trichloroethylene [EPA-HQ-OPPT-2016-0737]
Tetrachloroethylene [EPA-HQ-OPPT-2016-0732]
Methylene Chloride [EPA-HQ-OPPT-2016-0742]
Carbon Tetrachloride [EPA-HQ-OPPT-2016-0733]

Dear Sirs:

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) amended the Toxic Substances Control Act (TSCA) and established several regulatory timelines. Under TSCA § 6(b)(4)(D), EPA released scoping documents for the first ten chemicals targeted for evaluation under LCSA, including the chlorinated solvents trichloroethylene (TCE), tetrachloroethylene (perchloroethylene or PCE), and methylene chloride (dichloromethane or DCM). The general comments included in this submission are also applicable to the scoping document for carbon tetrachloride (CTC).

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers, distributors and users of chlorinated solvents. HSIA appreciates the opportunity to comment on problem formulation for the above-referenced scoping documents, as solicited in the notice announcing their release. 82 Fed. Reg. 31592 (July 7, 2017). In that notice, EPA acknowledged that the initial scoping documents did not achieve the quality anticipated for future scoping documents:

> "The first 10 chemical substances were not subject to prioritization, the process through which EPA expects to collect and screen much of the relevant information about chemical substances that will be subject to the risk evaluation process. As a result, EPA had limited ability to process all the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. Hence, the scope documents for the first 10 chemicals are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on drafts of these scope documents, as it intends to do for future scope documents."

One of the challenges for EPA in developing the required scoping documents was doing so prior to release of the final *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (Risk Evaluation Rule)*, 82 Fed. Reg. 33726 (July 20, 2017). Due to the acknowledged limitations of the initial scoping documents, EPA announced that it would:

> "publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals."

Typically, as will be discussed below, EPA treats Planning and Scoping and Problem Formulation as separate, albeit iterative, activities. The above statement indicates that EPA clearly has concerns with the quality of the Planning and Scoping element released in June and hopes to address those concerns through creation of a Problem Formulation document. Both elements are important in designing a credible risk assessment (or risk evaluation under LCSA). Recognizing that aspect, HSIA is pleased to submit the following comments for consideration by EPA in its development of the problem formulation documents for the four chlorinated organics (TCE, PCE, DCM, and CTC) found on the initial list of 10 chemicals under consideration.

General Recommendation

HSIA would strongly recommend that, in development of the problem formulation documents for the four chlorinated organics, EPA give serious consideration to its own guidance document *Framework for Human Health Risk Assessment to Inform Decision Making*. Although briefly mentioned in the Risk Evaluation Rule, there is no mention of the document in the June scoping documents for the four chlorinated compounds. We find this surprising, as application of the framework would appear to address many of the limitations acknowledged by EPA. As summarized in the 2014 document:

> "[t]he Framework for Human Health Risk Assessment to Inform Decision Making lays out a Framework for conducting human health risk assessments in support of decision making at EPA. It focuses on the planning and scoping and problem formulation steps, drawing on NRC (2009) and other advisory groups, and EPA experience. For example, the Framework addresses recommendations in the Silver Book (NRC 2009) on assuring the utility of risk assessment, which the Framework terms as being fit for purpose. . . [T]he NRC's 1983 four-step risk assessment paradigm is maintained, but there is increased emphasis on interaction between risk assessors and risk managers in planning the assessment to maximize utility. Emphasis on utility is maintained throughout the process, beginning with planning and scoping and continuing through the evaluation of the applicability of the risk assessment in informing decisions."

and

> "[a]pplication of the Framework, with its emphasis on problem formulation and the utility of the risk assessment, ultimately will result in better, more transparent choices among risk management options. This Framework builds on Agency guidelines, policies and guidance and is directed at improving risk assessment products but does not overturn or in any way change existing science policy decisions."

Specific Recommendations

Although the four chlorinated organics from the initial list of ten chemicals under consideration were not subjected to the LCSA prioritization process anticipated for chemicals considered in the future, it must be noted that all have been in commerce for decades and all should be considered "data-rich." As such, they all have a history of already being heavily regulated/controlled under a variety of existing federal and state programs. This makes them somewhat unique, particularly when compared against chemicals newly introduced into commerce, and raises some interesting problems in evaluating them under LCSA.

As mentioned earlier, the initial scoping documents for the four chlorinated organics were released prior to issuance of the Risk Evaluation Rule. In the preamble to that rule, which became effective on

September 18, EPA provided clarification on several issues that were problematic/unclear in the draft version released under the previous administration. In the following sections, HSIA addresses several of these specific issues in hopes that EPA will consider them during development of the problem formulation documents.

EPA's interpretation of its regulatory mandate under LCSA

In the Risk Evaluation Rule, EPA's clarified its regulatory mandate under LCSA:

> "EPA interprets the mandates under section 6(a)–(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur. . . ."

HSIA agrees with this position. As will be seen in several of the following recommendations, further broadening of that mandate for chemicals that are already subjected to extensive regulation presents serious conflicts both in assessing potential human health and environmental risks and in any subsequent risk management decisions. The focus should be restricted to chemicals in commerce from this point forward.

EPA should use discretion in its selection of conditions of use

One of the most contentious issues associated with the evaluation of risk under LCSA is "conditions of use." The issue focuses on the question "should any/all actual/potential uses of a chemical in the past/present/future be considered in the risk evaluation?" LCSA does not require the Agency to conduct full risk evaluations based on all conditions of use and nowhere in the law is "conditions of use" preceded by "all." Expansion of the term "conditions of use" beyond the intent of Congress may distract from and negatively impact EPA's ability to conduct meaningful risk evaluations in a timely manner.

EPA should exclude certain *de minimis* conditions of use

The four chlorinated organics included on the initial list are all used as intermediates in the synthesis of other chemicals. These are the largest uses of CTC and TCE. Such feedstock use takes place within closed systems in restricted-access facilities where workers are operating under Occupational Safety & Health Administration (OSHA) regulations with appropriate personal protective equipment (PPE). Given the nature of the chlorinated organics, a leak detection and repair (LDAR) program is typically in place and fugitive emissions are monitored. The only potential human exposure would be to on-site workers, whose risks are managed under a facility's health and safety program, which falls under the jurisdiction of OSHA. Potential off-site exposures would only occur at or beyond the facility fence-line, and air modeling of fugitive emissions typically shows maximum air concentrations occurring very close to the release point (*i.e.*, within the facility). In the preamble to the Risk Evaluation Rule, EPA addresses the issue of *de minimis* exposures such as these with the following rather ambiguous language:

> "EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only '*de minimis*' exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate."

Given our understanding of the use of these solvents as intermediates, HSIA believes there is a sufficient basis to exclude this "condition of use" from further consideration in the risk evaluation.

EPA should consider a tiered approach to address *de minimis* and/or heavily regulated exposures

For those situations where EPA is not comfortable excluding certain "conditions of use" based on anticipated *de minimis* exposures, HSIA recommends that the Agency consider a tiered approach for screening potential risks as an initial step in the risk evaluation. Although our preference would certainly be to exclude those *de minimis* and/or heavily regulated "conditions of use" during the scoping/problem formulation stage, we support EPA's recognition in the Risk Evaluation Rule that in order to efficiently carry out the LCSA Congressional mandate, EPA must maintain the flexibility to issue a decision on specific "conditions of use" in a tiered, staged approach.

Legacy sources of exposure should not be addressed under LCSA

HSIA recommends that legacy sources of exposure should be excluded from the risk evaluation process under LCSA. Legacy sources of exposure typically refer to historical releases of a chemical to the environment associated with misuse or disposal. Although legacy environmental sources of exposure certainly exist for the four chlorinated organics, they have been effectively managed for decades under various federal programs (*i.e.*, CERCLA, RCRA, CAA, etc.). Many states also have stringent programs for addressing legacy contamination from these chemicals. Management of legacy contamination through the various federal and state programs is already risk-based and adding an additional risk-management program to the existing mix would be duplicative and not needed. The following statement from the preamble to the Risk Evaluation Rule indicates that EPA feels it could "exercise its discretion" on decisions relating to exclusion of a particular condition of use.

> "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks."

From a practical perspective, it is difficult to conceive how risks from a legacy source of exposure would even be managed under LCSA. For the four chlorinated organics, once a legacy exposure source (*i.e.*, existing environmental contamination) is discovered, responsibility for management of any human health or environmental risk would be assumed by the state. If the source was sufficiently large and generated a sufficiently high Hazard Ranking Score (HRS), it could be classified as a Superfund site under CERCLA.

Protection from workplace exposures to chemicals is the primary responsibility of OSHA, not EPA

As noted above, EPA has exclusionary discretion for "a condition of use [*i.e.*, exposure] that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks." As originally enacted and as updated by LCSA, TSCA requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."[1] It has been clear since passage of the Occupational Safety and Health Act in 1970 that workplace protection is the primary responsibility of OSHA.

The LCSA eliminated the requirement in TSCA § 6(a) that EPA protect "against [unreasonable] risk using the least burdensome requirements," but did not materially change the existing framework that

[1] TSCA § 9(d).

requires unreasonable risks to be addressed under statutory authority other than TSCA wherever possible. EPA's longstanding interpretation of this framework is as follows:

> "Under section 9(a)(1) of TSCA, the Administrator is required to submit a report to another Federal agency when two determinations are made. The first determination is that the Administrator has reasonable basis to conclude that a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. The second determination is that the unreasonable risk may be prevented or reduced to a sufficient extent by action taken by another Federal agency under a Federal law not administered by EPA. Section 9(a)(1) provides that where the Administrator makes these two determinations, EPA must provide an opportunity to the other Federal agency to assess the risk described in the report, to interpret its own statutory authorities, and to initiate an action under the Federal laws that it administers.
>
> "Accordingly, section 9(a)(1) requires a report requesting the other agency: (1) To determine if the risk may be prevented or reduced to a sufficient extent by action taken under its authority, and (2) if so, to issue an order declaring whether or not the activities described in the report present the risk described in the report.
>
> "Under section 9(a)(2), EPA is prohibited from taking any action under section 6 or 7 with respect to the risk reported to another Federal agency pending a response to the report from the ether Federal agency. There would be no similar restriction on EPA for any risks associated with a chemical substance or mixture that is not within the section 9(a)(1) determinations and therefore not part of the report submitted by EPA to the other Federal agency."[2]

It was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. When TSCA was enacted in 1976, Representative James Broyhill of North Carolina indicated that "it was the intent of the conferees that the Toxic Substance [Control] Act not be used, when another Act is sufficient to regulate a particular risk."[3] TSCA § 9(a) is substantively unchanged by the LCSA. The House Energy and Commerce Committee Report states: "H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals," and further clarifies that "while § 5 makes no amendment to TSCA § 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety."[4]

EPA applied this statutory directive in determining that the risk from 4,4' methylenedianiline (MDA) could be prevented or reduced to a significant extent under the OSH Act, and referring the matter for action by OSHA.[5] And in an analysis of TSCA § 9, EPA's Acting General Counsel concluded that

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[2] 4,4'-Methylenedianiline; Decision to Report to the Occupational Safety and Health Administration, 50 Fed. Reg. 27674 (July 5, 1985). EPA also has acted under § 9(a) to refer 1,3-butadiene and glycol ethers to OSHA, 50 Fed. Reg. 41393 (Oct. 10, 1985) and 51 Fed. Reg. 18488 (May 20, 1986), respectively, and to refer dioxins in bleached wood pulp and paper products to the Food and Drug Administration, 55 Fed. Reg. 53047 (Dec. 26, 1990).

[3] 122 Cong. Rec. H11344 (Sept. 28, 1976)

[4] H. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28.

[5] 50 Fed. Reg. 27674 (July 5, 1985).

"Congress expected EPA – particularly where the Occupational Safety and Health Act was concerned – to err on the side of making referrals rather than withholding them."[6]

If EPA were to identify a category of exposure deemed to present a risk that is unreasonable, these considerations indicate that referral under § 9(a) would be the appropriate course.[7] It is clear from Section 9(a) that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks.

EPA codified this principle in the Risk Evaluation Rule, 40 C.F.R. §702.39. EPA should adopt the OSHA permissible exposure limits (PELs) as the appropriate screening levels for potential risks to workers. If the 90th percentile estimates from the 8-hour time-weighted average (TWA) exposure concentrations are at or below the OSHA PELs, EPA should conclude a condition of no significant risk for worker exposures. However, it is possible that EPA could, if scientifically appropriate, decide to apply more recent American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) to evaluate potential risks to workers.

Occupational exposure limits, such as OSHA PELs and ACGIH TLVs, are derived to be protective for occupational exposures. The values are typically based on occupational epidemiology studies and, therefore, are especially relevant for worker populations. For example, occupational studies by their very nature include consideration of the healthy worker effect.[8] Occupational exposure limits also consider other factors unique to the workplace, such as technical feasibility. In general, occupational exposure limits should be considered protective for worker exposures. Such limits and their bases should be part of worker risk evaluations under the new TSCA.

Risk evaluations conducted under LCSA should be state-of-the-art

There have been significant developments in the science of risk assessment and in our understanding of mode of action for cancer and other apical endpoints in recent years. HSIA is encouraged that EPA has acknowledged these developments in the Risk Evaluation Rule and appears committed to including them in risk evaluations conducted under LCSA. Many of these developments are the result of concerns with EPA's IRIS program. HSIA believes that the following are necessary components of a state-of-the-art risk evaluation and should be part of the problem formulation documents.

Systematic Review: Although several of the chemicals from the initial list of ten to be evaluated under the amended TSCA are relatively data-rich, it is essential that a systematic review be undertaken to ensure that all existing hazard data are considered. The IRIS evaluation of TCE, for example, was completed in 2011 and an examination of that document reveals that many of the studies referenced are now more than a decade old. Although EPA indicated that many of the principles of systematic review were considered

[6] Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2.

[7] As noted above, TSCA § 9(a) provides that if the Administrator has reasonable basis to conclude that an unreasonable risk of injury is presented, and he determines, in his discretion, that the risk may be prevented or sufficiently reduced by action under another federal statute not administered by EPA, then the Administrator shall submit a report to that agency describing the risk. In the report, the Administrator shall request that the agency determine if the risk can be prevented or sufficiently reduced by action under the law administered by that agency; if so, the other agency is to issue an order declaring whether the risk described in the Administrator's report is presented, and is to respond to the Administrator regarding its prevention or reduction. The Administrator may set a time (of not less than 90 days) within which the response is to be made. The other agency must publish its response in the Federal Register. If the other agency decides that the risk described is not presented, or within 90 days of publication in the Federal Register initiates action to protect against the risk, EPA may not take any action under § 6 of TSCA.

[8] A healthy worker effect is based on observations in occupational epidemiology studies that workers usually exhibit lower overall death rates than the general population because the severely ill and chronically disabled are ordinarily excluded from employment (Li *et al.* 1999).

during the TCE IRIS evaluation, there have been significant developments in that process over the past decade. At the very least, the systematic review should consider all existing hazard data and, consistent with current approaches, publish acceptance criteria, including criteria to assess study quality, which are then used in the selection of key studies.

HSIA would recommend that a similar approach be applied to exposure data used for the risk evaluation. For example, a systematic review of air monitoring data should exclude data generated prior to the effective date of a National Emission Standard for Hazardous Air Pollutants which limited the emissions of a particular chemical from covered sources. Although EPA provides a fairly lengthy discussion on systematic review in the preamble to the Risk Evaluation Rule, it did not codify a definition for systematic review. Many of the elements of systematic review do, however, appear in the codified definition of "weight of scientific evidence" provided below.

Consideration of Best Available Science: HSIA strongly endorses the use of best available science in risk evaluations conducted under LCSA. Although Section 702.33 of the Risk Evaluation Rule provides a detailed definition of "best available science," the overarching principal is science that is reliable and unbiased. Several of the chlorinated solvents have suffered from EPA's reliance on scientific studies that were considered substandard by the scientific community. HSIA is hopeful that EPA's commitment to consideration of best available science, when combined with a formal systematic review process, will yield risk evaluations that are reliable.

Consideration of New Data: HSIA supports EPA's position on the acceptance of new data for consideration in the risk evaluation.

> "EPA does not intend to preclude the generation of new scientific information to inform risk evaluations, however, as mentioned in the discussion of reasonably available information, the extent to which EPA will consider any newly generated information in a risk evaluation will depend on the statutory deadlines."

Application of Weight of Scientific Evidence Approach: As discussed above, Section 702.33 of the Risk Evaluation Rule defines "weight of scientific evidence" as:

> ". . . a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."

Similar language regarding the "weight of scientific evidence" was included in the scoping documents for TCE , PCE , DCM and CTC released in June 2017 [excerpt from the TCE scoping document follows]:

> "EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent."

Whether or not a definition for systematic review is codified in the Risk Evaluation Rule is less important than EPA's commitment to integrate the process into risk evaluations conducted under LCSA. HSIA strongly supports that commitment for both hazard and exposure data.

Peer Review: Although the proposed Risk Evaluation Rule only provided lip-service to the concept of peer review, HSIA strongly supports EPA's commitment to the peer review process as described in the preamble to the final rule:

> "In addition to any targeted peer review of specific aspects of the analysis, the entire risk assessment will also undergo peer review [emphasis added], as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination. "

EPA's commitment to the peer review process under TSCA has, to date, been uneven. Although the TSCA Work Plan Chemicals Assessment for TCE, conducted in 2012, was subjected to external peer review, the final document contained an exposure scenario (*i.e.*, condition of use) that was not even included in the draft. Despite lack of peer review for that condition of use, EPA used the results of the risk assessment as the basis for a proposed ban.

Public Comment Period: LCSA requires that EPA allow for no less than a 30-day public comment period on a draft risk evaluation, prior to publishing a final risk evaluation. HSIA recommends that EPA allow at a minimum a 60-day public comment period following release of the draft problem formulation documents given their obvious importance in setting precedent for the program moving forward. Indeed, a public meeting to review and discuss public comments on the draft problem formulation documents could greatly facilitate agreement on the final product (*i.e.*, the risk evaluation).

Clearly, the scenarios examined in the 2014 TSCA Work Plan Chemicals Assessments should be re-evaluated. Language in the scoping documents for TCE and DCM, released by EPA in June 2017, indicates that conditions of use previously evaluated in 2014 TSCA Work Plan Chemical Risk Assessments may not be re-evaluated under the Risk Evaluation Rule. HSIA urges EPA to reconsider this position as part of problem formulation, for several reasons. First, as already mentioned, between publication of the peer-reviewed draft assessment for TCE in 2012 and release of the final version in 2014, EPA introduced a new "condition of use" (*i.e.*, spot cleaning) which was not subjected to peer review. Second, the Risk Evaluation Rule, which promulgated the procedure(s) to be followed in conducting a risk evaluation to satisfy requirements under LCSA, was not published until July 20, 2017, three years after finalization of the Work Plan Chemical Assessments for TCE and MC. All significant "conditions of use" should be evaluated in compliance with the Risk Evaluation Rule, which requires significant aspects not addressed or applied in the previous risk assessments, such as consideration of best available science and application of a weight of the scientific evidence approach.

To facilitate EPA's review of these uses, HSIA is submitting comments on the earlier proposed rules (and related risk assessments) to the relevant dockets.

EPA's approach for evaluating environmental impacts under LCSA is problematic

Under LCSA, EPA is required to evaluate potential chemical impacts on the environment and HSIA has serious concerns about the approach described in the final Risk Evaluation Rule. The scoping documents for the four chlorinated organics state that:

> ". . . manufacturing, processing, use and disposal . . . . . can result in releases to air, water, sediment and soil. EPA expects to consider exposures to the environment and ecological receptors that occur via these exposure pathways or media . . . . . in conducting the risk evaluation . . . ."

The Risk Evaluation Rule appears to expand the potential scope for the evaluation of environmental impacts even further. Under §702.43(4) (*i.e.*, Considerations for environmental risk evaluations), the rule states:

> "For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance."

In addition to being concerned about the level of effort required to carry out such an activity, HSIA is concerned that such an evaluation would have to be location-specific. If, for example, EPA is interested in evaluating potential environmental impacts from a manufacturing facility, those impacts will have to be based on either measured or modeled media concentrations. The fate and transport of chemicals into air, soil, sediment, and surface water is known to be influenced by factors that are location- and site-specific and any adverse impacts will be applicable to that specific facility only. The air modeling of emitted chemicals from a manufacturing facility into environmental media surrounding that facility, for example, will be influenced by many factors, including local meteorology, terrain, proximity to surface water bodies, and distance to the facility boundaries, among others.

As described, the evaluation of environmental impacts under LCSA could result in a situation where a "condition of use" is found to be associated with unacceptable environmental impacts, yet the "condition of use" would only be relevant at a specific facility. That same "condition of use" could be acceptable at another facility operating under the exact same conditions, creating a real risk management dilemma.

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HSIA appreciates the opportunity to provide these comments on this important step of problem formulation.

Respectfully submitted,

Faye Graul

Faye Graul,
Executive Director

EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA

This response to comment document addresses cross cutting public comments that may be applicable to issues impacting all ten chemicals. The responses here represent EPA's preliminary reactions to some of the comments received, as the Agency has not reached final decisions on the approaches to the 10 risk evaluations. The Agency invites the public to provide additional comments on these Problem Formulation documents if their comments/issues have not been sufficiently addressed.

General comments

1. Many commenters asked for clarification on how the problem formulations will be different than the scope documents. Commenters added that these scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations (0741-0059, 0741-0060). One commenter added that "it is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. The commenter believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified.

   Response: EPA agrees that TSCA requires that scope documents include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. EPA believes the scope documents did that, although without the level of specificity EPA expects for future risk evaluations. As explained in each of the scope documents,

   "To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

   Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for [chemical name]."

   EPA has published the Problem Formulation documents which refine these 10 scope documents. The conceptual models and analysis plans in the problem formulation documents more clearly identify the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations the Administrator expects to consider in risk evaluations for the first ten chemicals. Additional specificity around some of these general components (e.g., particular exposure parameters, points of departure for hazards, susceptible subpopulations based on greater susceptibility) of a risk evaluation cannot be provided until data and models are reviewed and analyses conducted. These activities and further analyses occur during the Analysis Phase of risk evaluation and will be presented in the Draft Risk Evaluation.

Conditions of Use

2. EPA received a number of comments regarding the conditions of use. Commenters urged EPA to consider the chemical substance as a whole and therefore to consider all conditions of use, and that EPA does not have discretion to ignore certain uses (0741-0059, 0735-0052), including de minimis uses (0741-0061). Other commenters added that EPA should consider reasonably foreseeable uses like accidents, misuses, and off-label uses, whole lifecycle of the chemical including legacy, and non-TSCA uses (0741-0061, 0741-0062, 0741-0056, 0741-0029). One commenter specifically questioned the exclusion of accidents, stating that the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks (0741-0059).

   Specifically, regarding legacy uses, two commenters added that legacy uses should be considered (0735-0052) (0741-0057), and others noted that there are six chemicals that contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. These commenters stated that ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations (0741-0060, 0741-0062). Additionally, one commenter added that by-product or contaminant uses should also be added (0741-0057).

   Response: As discussed at length in the preamble to the final risk evaluation rule, based on legislative history, statutory structure and language, and other evidence of Congressional intent, EPA has identified certain activities that may generally not be considered to be conditions of use. EPA does not generally intend to include intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in a chemical substance's risk evaluation. EPA's judgment is supported by the legislative history, and public comment suggesting that "the term 'conditions of use' is not intended to include 'intentional misuse' of chemicals." See, for example Senate Report 114–67, page 7. Similarly, EPA interprets the mandates under section 6(a)–(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), and consequently does not generally intend to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal.

   EPA further explained that it may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. This includes uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks. EPA may determine that there are appropriate regulatory safeguards in place for a particular use or that a particular use is de minimis, and that these uses can be excluded from further assessment as part of the risk evaluation. Finally, EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental

statutes and which EPA does not expect to include in the risk evaluation. See, 82 Fed Reg at 33729-33730 for further details on EPA's reasoning.

EPA also indicated in the preamble to the Risk Evaluation rule, and again in the chemical scope documents, that it intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping. EPA went on to explain that there may be several different technical and policy perspectives in which to consider evaluating the risks of impurities, including to evaluate the potential risks within the scope of the risk evaluations for the impurity itself, within the scope of the risk evaluation for the separate chemical substances that bear the impurity, and not including the impurity within any risk evaluation where EPA has a basis to foresee that the risk from the impurity would be *de minimis* or otherwise insignificant.

The problem formulation document for each of the first 10 chemicals has been refined based on comments and input on the scope documents. The problem formulation more clearly presents what conditions of use and associated exposure pathways will be evaluated in the risk evaluation and provides rationales for EPA's decisions.

Systematic Review

3. Two commenters request that the Agency conduct systematic review to identify the hazard as these methods will strengthen and increase transparency. Specifically, 0741-0052 stated that EPA should conduct hazard identification by following systematic review processes that integrate animal, human, and mechanistic evidence and that EPA should heed the NAS recommendation to conduct risk evaluations by identifying any existing systematic reviews for a chemical substance, determining if the reviews are of high quality, and for those that are, building upon the reviews by incorporating any more recent studies that may have become available since the review was conducted (0741-0052). Another commenter provided a number of ways to improve the Agency's literature search and systematic review strategies to strengthen its evaluations and increase transparency (0741-0057).

   Response: As stated in the Risk Evaluation rule, EPA believes that integrating systematic review into the TSCA risk evaluations is critical to meet the statutory requirements of TSCA. EPA agrees that there are universal components of systematic review that EPA intends to apply in conducting risk evaluations. EPA has also concluded it would be premature to codify specific systematic review methods and criteria since these may change as the Agency gains more experience conducting TSCA risk evaluations.

   Along with the problem formulation documents, EPA is publishing a supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*, which contains details about the systematic review process and the evaluation strategy for assessing data quality that OPPT plans to use for these first ten chemical risk evaluations. Integrating systematic review principles into the TSCA risk evaluation process is critical to develop transparent, reproducible and scientifically credible risk evaluations.

EPA/OPPT plans to implement a structured process of identifying, evaluating and integrating evidence for both the hazard and exposure assessments developed during the TSCA risk evaluation process. The systematic review process will use existing assessments as a starting point to identify relevant references and supplement these with any more recent information. It is expected that new approaches and/or methods will be developed to address specific assessment needs for the relatively large and diverse chemical space under TSCA. Thus, EPA/OPPT expects to document the progress of implementing systematic review in the draft risk evaluations and through revisions of the *Application of Systematic Review in TSCA Risk Evaluations* document, and publication of supplemental documents.

Exposure

4. A number of commenters provided input regarding how the Agency will assess chemical exposures, specifically with regard to engineering controls. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). (0741-0059, 0741-0062, 0741-0029, 0741-0057). Another commenter added that, in evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective. The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls (0741-0060).

   Response: OPPT's approach for developing exposure assessments for workers is to use best available information to construct realistic exposure scenarios based on data and information regarding real-world use of chemicals. When appropriate, in the risk evaluation, OPPT will use exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-by-case basis for a given chemical.

5. There were a number of comments urging EPA to assess aggregate exposures within populations in the problem formulations, and stating that failing to do so would underestimate the risk of the chemicals. (0735-0052, 0741-0057, 0741-0060, 0741-0061, 0741-0029)

   Response: The statute requires that the Agency describe whether aggregate (or sentinel) exposures were considered, see 15 USC 2605(b)(4)(F)(ii); whichever exposure assessment method is ultimately used will be accompanied by an explanation in the Risk Evaluation. In conducting an aggregate exposure assessment, EPA may also include exposures from non-TSCA uses, e.g., as part of background; whether and how to account for such exposures will be

evaluated on a case-by-case basis. EPA will consider whether to assess aggregate exposure when developing the exposure assessment during the Analysis Phase of the Risk Evaluation.

6. Two commenters asked how EPA will incorporate cumulative risk, as well as aggregate, in the first 10 risk evaluations. Commenters added, to properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. (0741-0060, 0741-0061)

   Response: Cumulative exposure is not required under the statute. EPA retains the discretion to conduct a cumulative assessment but has not yet determined whether to do so for any of the first 10 risk evaluations. However, EPA may ultimately determine that for a certain chemical or category a cumulative exposure assessment is appropriate for certain endpoints.

Hazard

7. One commenter asked EPA not to prejudge the absence of adverse effects for particular end-points at the scoping stage but to defer such conclusions until the systematic review phase of its risk evaluation as the law requires (0741-0060).

   One commenter expressed concern that EPA says in all the chemical scoping documents in the Section on Environmental Hazards that it expects to consider other studies, including data from alternative test methods such as computational toxicology, bioinformatics, high-throughput screening methods, read-across data, etc. Many of these alternative test methods, and particularly their application to risk assessment, are still emerging and, although promising, have serious limitations. However, if utilized prematurely or incorrectly, these tools could allow for the rapid and erroneous exoneration of harmful chemicals. These tools lack complete biological coverage, cannot presently evaluate the potential toxicity associated with chemical metabolism and absorption, and have the potential for high false negatives relative to whole animal studies (0741-0062).

   Response: EPA does not intend to prejudge any conclusions before completing the systematic review process supporting the risk evaluations. OPPT is aware of the status of alternative test methods with regard to the methodological validation, standardization and acceptance (e.g., established OCSPP or OEC Test Guideline vs. basic research approach). Regardless of the level of regulatory or international recognition, data from other studies and alternative test methods can inform risk evaluation if they are determined to be consistent with the best available science and can inform the weight of the scientific evidence. Like other, more traditional testing studies, studies conducted using non-guideline approaches or using alternative test methods will be evaluated for quality and relevance following the process described in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*. In addition, all risk evaluations will be subject to public comment and independent peer review. OPPT anticipates use of data from alternative test methods.

   TSCA section 26(h) requires that, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, EPA must use scientific information, technical procedures, measures, methods, protocols, methodologies, or models consistent with the best available

science. TSCA section 26(i) requires EPA to make decisions under TSCA sections 4, 5, and 6 based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).

8. One commenter stated that three chemicals (carbon tetrachloride, methylene chloride and 1-bromopropane) have data showing a high ozone depletion potential and that this should fall within the scope of the risk evaluation (0742-0060).

   Response:

   Regulation of ozone-depleting substances (ODS) falls under the jurisdiction of the Clean Air Act, administered by EPA's Office of Air and Radiation. Because ozone depletion risks are adequately assessed and effectively managed under the Clean Air Act, EPA does not expect to include ozone-depletion potential in risk evaluations for carbon tetrachloride, methylene chloride or 1-bromopropane. EPA regulations under Sections 601-607 of the Clean Air Act phase out the production and import of class I and class II ODS ([HYPERLINK "https://www.epa.gov/ods-phaseout"]) with limited exceptions. Carbon tetrachloride is subject to these regulations, addressing its ozone-depletion risks. Furthermore, under Section 612 of the CAA, EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ODS. New chemicals that are proposed as substitutes are reviewed in coordination with OCSPP's New Chemicals Program, and significant new uses of existing chemicals are also reviewed under the SNAP program. Various environmental and health risks of methylene chloride and 1-bromopropane (n-propyl bromide), including their ozone-depletion potential, have been evaluated for specific uses under the SNAP program.

Health Protective Defaults

9. A number of commenters urged EPA to use health-protective defaults if the agency lacks information specific to a chemical, and health-protective methods to quantify risk when characterizing risk (0741-0052, 0741-0057, 0741-0062). Specifically, for cancer, a commenter highlighted the NAS recommendation that EPA include a factor to account for human variability in response to carcinogens, as EPA's current approach inaccurately assumes that there is no variability in response. Similarly, EPA should increase or add factors that address cancer and non-cancer susceptibility during early life stages (0741-0057).

   One commenter urged EPA not to use MOE (margin of exposure) as an analysis method in the risk evaluation process, as MOE is not an estimate of risk—it is a single number that is a version of the "bright line" approach like the Reference Dose (or Reference Concentration for inhalation doses) (0741-0057).

   Response: EPA does not want to *a priori* preclude the use of any methods or data types, to allow its evaluations to change as science advances. EPA will utilize current policies, models, and screening methods, but is committed to being consistent with the best available science and weight of the scientific evidence approaches to guide the Agency in using this information. EPA recognizes the advancing science to inform risk evaluation and will not discourage the use of new methods as long as they are consistent with the standards in section 26 of TSCA. EPA also recognizes that different approaches require different types and amounts of data and will select

and employ methods that are fit for purpose within the context of a particular risk evaluation. In some cases, it may be necessary to utilize default parameters in modeling and risk calculations, and to utilize conservative assumptions, whereas in other cases assumptions may be replaced with specific or specialized data. It should also be noted, in addition, their use will be peer reviewed, and the public will have the opportunity to comment on them during the public comment periods.

EPA has utilized the MOE approach in previous risk assessments, citing its utility. However, EPA does agree with comments that there are numerous ways to characterize risk, of which MOE is just one. There will be risk scenarios where one approach may be better than another and, as commenters correctly pointed out, the science of risk characterization is still evolving, particularly for non-cancer hazards. Hence, OPPT will use risk characterization approach(es) suitable for the purpose of the risk evaluation and that the best available science and data support. EPA does not agree with the commenter that the use of MOEs is never appropriate.

Confidential business information (CBI)

10. A number of commenters added comments regarding CBI. Two requested EPA require that claims of confidential business information be fully substantiated by industry and not used to conceal critical information from the public (0741-0052, 0741-0057, 0074-0059). Another added that EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired (0741-0060).

    One commenter added that the strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available EPA must review it (0741-0059).

    Additionally, this commenter raised the question as to whether this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. Historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act (0741-0059).

    Response: TSCA requires that CBI claims must be asserted and substantiated concurrently with the submission of information, except for information that is deemed exempt under TSCA section 14(c)(2).

    The risk evaluation rule does clarify that the agency does consider CBI as "reasonably available information" and will utilize it in risk evaluations were relevant.

The *Strategy for Conducting Literature Searches for each TSCA Scope document* described the procedure for searching the public literature which does not include searching "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information". However, OPPT is searching internal information it may possess as part of the process of conducting the risk evaluations. This is discussed in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.*

EPA will comply with TSCA section 14 review and disclosure requirements for data/information that is claimed confidential and deemed relevant for the risk evaluation.

Potentially exposed and susceptible subpopulations

11. Commenters provided feedback regarding EPA's approach to identifying "potentially exposed or susceptible subpopulations." One commenter suggested that EPA address susceptible sub-populations, following recommendations from the National Academies of Sciences (NAS) to identify susceptible sub-populations based on established extrinsic and intrinsic factors that increase vulnerability (0741-0057).

    Another commenter suggested the language provided in the scopes was general "boilerplate" descriptions of such subpopulations, adding that further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor that TSCA requires (0741-0060). Similarly, a commenter asked for more clarification in the problem formulation documents of those populations with greater susceptibility (0741-0059).

    Another commenter encouraged EPA to consider for every chemical review: (1) occupational exposures that are often at much higher exposure levels than the general public, both acutely and chronically, and can be concurrent with other chemical exposures at the workplace; (2) fence-line communities who also face multiple exposures to multiple chemicals and suffer from many chronic health conditions and health inequalities; (3) sensitive time periods during life, such as pregnancy and during childhood; (4) tribal communities where cultural and lifestyle considerations may result in very different exposure profiles and where there are often disproportionate adverse health outcomes; and (5) general variability in human responses. The commenter encouraged EPA to actively seek input from fence-line and other impacted communities, occupational workers at manufacturing, processing, distributing, or recycling facilities, concerned members from the public, and tribal communities and incorporate their concerns in the Agency's evaluations where appropriate." (0741-0029)

    A commenter added comments specifically regarding occupational exposure: Occupational workers exposed during the manufacture, processing, disposal, etc. of these chemicals should always be considered separately as a susceptible population. Furthermore, the consideration of exposed workers should always include the potential for pregnant women and consider both women and men of childbearing age as a vulnerable population when assessing the risk (0741-0029 and 0741-0059).

Finally, one commenter urged the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. The commenter also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment (0741-0061).

Response: While EPA wholly agrees that protecting potentially exposed or susceptible subpopulations is an important part of EPA's mandate, the process for identifying the subpopulations considered in each risk evaluation will be case specific and, consistent with the directive in section 6(b)(4)(A), tailored as relevant to the risk evaluation. Furthermore, EPA will use the best available science and prevailing guidance, such as recommendations of the NAS, in defining and assessing such subpopulations.

Every risk evaluation must consider any 'potentially exposed or susceptible subpopulations' determined to be relevant to the risk evaluation under the conditions of use. However, potentially exposed or susceptible populations and subpopulations can vary depending on the chemical and conditions of use being evaluated. EPA is required by statute to consider relevant potentially exposed or susceptible subpopulations, which could include children, pregnant women, and other subpopulations as appropriate for the assessment. For example, when appropriate, EPA will include specific life-stages exposure scenarios which may be more representative of various exposures that affect children.

Likewise, if workers are determined to be a population likely to be exposed to a chemical during its conditions of use, this population would be included as a 'potentially exposed or susceptible subpopulation' and therefore considered in the risk evaluation. In fact, in the scope documents, EPA identified both workers and consumers as susceptible subpopulations on the basis that they are more exposed than the general population to chemicals and/or products that the general population does not work with or use. EPA acknowledged in the scope documents that measurement and evaluation methods for these, and potentially other, subpopulations is still being refined.

EPA welcomes information from communities and will use it to further refine risk evaluations.

To this end, EPA has already sought input from specific populations and public health experts in implementing TSCA and will continue to do so. For example, EPA has had discussions on several occasions with the National Tribal Toxics Council to receive input on tribal lifeways and exposures. OPPT and the NTTC continue to collaborate on ways to consider tribes in conducting potentially exposed or susceptible subpopulations analyses for Draft Risk Evaluations. OPPT has also had several meetings with AFL-CIO about workers as potentially exposed or susceptible subpopulations and ways in which worker exposure information could be identified and provided for use in the risk evaluation process. OPPT has also sought advice and input regarding children as a susceptible subpopulation from the Children's Health Protection Advisory Committee (CHPAC) through a meeting and recommendations addressing the formal request from EPA for guidance on how risk evaluation should address children. CHPAC's recommendations can be found [HYPERLINK "https://www.epa.gov/sites/production/files/2017-04/documents/2017.03.30_chpac_tsca_letter.pdf"].

IRIS Assessments

12. A few commenters urged EPA to use existing IRIS assessments (0741-0061, 0741-0062). Specifically, EPA should rely on existing IRIS assessments for hazard identification, and moving forward, EPA should complete hazard identification or add additional studies only through a systematic review process, which integrates animal, human and mechanistic evidence as recommended by the recent NAS report (0741-0057). EPA does not need to revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address (0074-0060).

    Response: As discussed in the scope documents, where applicable, OPPT has used IRIS documents as a starting point for identifying key and supporting toxicity studies and initial hazard identification. However, EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. Specifically, EPA will screen information developed after the completion of any IRIS assessment and evaluate the relevant information using OPPT's structured process described in the documents *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act* (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.*

Information Gathering

13. EPA received a number of comments on information gathering.

    "EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA [sections] 4 and 8 to obtain additional information. The scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is reasonably available information. Additionally, any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps." (0741-0059).

    Response: The commenter is correct, as the scope documents should refer to "reasonably available information", not "readily available". In the risk evaluation rule, EPA defined reasonably available information to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. Below EPA has collated a non-exhaustive list of the information activities associated with collecting reasonably available information. EPA notes that it selected the first 10 chemicals for risk evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development.

Generate: EPA explained in the risk evaluation rulemaking that reasonably available information includes information that could be generated through testing, where that information can be generated and synthesized within the statutory timeframes and would be of sufficient value to merit the testing. As of now, EPA has not identified the need for any such testing for the first 10 chemicals. In the timeframe allotted to initiate the risk evaluation process and develop the scoping documents for the initial ten chemicals subject to risk evaluation following the 2016 amendments to TSCA, EPA consulted a variety of information sources, both internally and externally, and currently believes the information obtained through these investigations is sufficient to make the necessary determinations. As we have previously indicated (for instance, in the scope documents for the first ten chemicals), in the future prioritization (and pre-prioritization) processes, EPA will have additional time prior to risk evaluation to evaluate data landscapes and judge whether testing would be appropriate. While the timeframes for these first 10 risk evaluations have necessarily constrained EPA's ability to require testing, EPA does not currently see the need for testing to complete these risk evaluations.

Obtain: EPA conducted extensive and varied data gathering activities for each of the first 10 chemicals, including:

(1) Conducted extensive and transparent searches of public databases and sources of scientific literature, government and/or industry sector or other reports, etc. [See supplemental file, Strategy for Conducting Literature Searches, associated with each of the ten chemicals on the chemical's webpage].
(2) Searched EPA TSCA 8(e) and CBI submission holdings for data on the first ten chemicals.
(3) Consulted a variety of sources to identify conditions of use of the initial ten chemicals. These sources included information reported to EPA (including Chemical Data Reporting and the Toxics Release Inventory), literature searches, proprietary reports, trade publications, and reports developed for prior EPA and international assessments. To identify formulated products containing <chemical>, EPA searched for safety data sheets (SDS, formerly referred to as material safety data sheets (MSDS)) using internet searches, EPA Chemical and Product Categories (CPCat) data, the National Institute for Health's (NIH) Household Product Database, and other resources in which SDS could be found. Each SDS was then cross-checked with company websites to make sure that each product SDS was current. EPA also communicated with companies, industry groups, international regulatory agencies, and non-governmental organizations, to make sure the list of uses was correct, complete, and up-to-date. A preliminary list of uses was presented to the public for comment ahead of a public meeting as part of a use document for <chemical>. Those public comments as well as information from other engagements with stakeholders were integrated into this scoping document.
(4) Conducted a market analysis of conditions of use using proprietary databases and repositories.
(5) Conducted many outreach meetings with chemical manufacturers, processors, chemical users, non-governmental organizations, trade organizations, and other experts, including other State and Federal Agencies (e.g., Dept of Defense, NASA, OSHA, NIOSH, FDA and CPSC) for each of the initial ten chemicals [See Docket(s)

[HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca" \l "ten"]] to support development of conditions of use documents [see Dockets
[HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca" \l "ten"]] and scope documents

(6) Published conditions of use documents, solicited public comment/input on conditions of use of the initial ten chemicals, convened a public meeting and opened dockets to receive written public comments. See the following link for additional information: [HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca"]
(7) Solicited public input on Scope documents and encouraged submission of additional data/information regarding the scope for each of the initial ten chemicals
(8) Consulted existing systematic review approaches and methods to inform development of data evaluation step of systematic review under TSCA
(9) Worked with chemical manufacturers, industry associations, other federal agencies, state governments, unions, non-governmental organizations, and international regulatory partners to discuss additional data/information that would inform risk evaluations and scenarios where people could be exposed to the initial ten chemicals. As a result, EPA received additional study reports regarding hazard information, (e.g. PV29), occupational monitoring data from DoD, data from OSHA on worker exposures, and a variety of information from a wide swath or stakeholders on how chemicals are used in specific industries.
(10) Published Problem Formulation documents and solicited public input to obtain further information useful for developing the draft risk evaluation

Synthesize: EPA has synthesized reasonably available information in several phases during the risk evaluation process for the first chemicals, as follows:

(1) Developed conditions of use documents that synthesize the data/information obtained from searches and meetings with stakeholders for each the initial ten chemicals.
(2) Conducted title and abstract screening on all references obtained from the literature searches, synthesizing this information into 'on topic' and 'off topic' bins for all ten chemicals [see supplemental file, Bibliography, for each of the ten chemicals on the chemical's webpage].
(3) Developed Scope documents that synthesize conditions of use and lifecycle information for each chemical to describe the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in the risk evaluation and link them to the plan for the analyses to be included in the risk evaluation.
(4) Synthesized existing methods/approaches to systematic review to develop the evaluation strategies to assess data/information quality as described in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*
(5) Synthesized additional input/data/information received on scope documents in developing problem formulation documents that synthesize conditions of use and lifecycle information for each chemical to describe the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in the risk evaluation and link them to the plan for the analyses to be included in the risk evaluation.

(6) Consulted within EPA, across major media programs, to integrate and synthesize (cross-walk) the nexus between TSCA and other major media statutes and regulatory programs (e.g., CAA, CWA, SDWA, RCRA).

EPA agrees that it makes sense to view information that can be obtained through testing as "reasonably available" in some instances – especially information that can be obtained through short-term testing, where it can be obtained within the relevant statutory deadlines and the information would be of sufficient value to merit the testing. EPA will consider use of its information gathering authorities under section 8 on a similar basis – i.e., considering the statutory deadlines and the value the additional information would likely have in reducing uncertainty in its fit-for-purpose evaluations. As discussed in the prioritization rulemaking, EPA will seek to generally ensure that sufficient information to complete a risk evaluation exists and is available to the Agency prior to initiating the evaluation. For these first ten risk evaluations, EPA believes that these are generally data-rich chemicals, and the use of our data gathering authority is not warranted at this time. However, EPA also recognizes that there may be circumstances where additional information may need to be developed within the time frames of the risk evaluation process. This may include information developed through the use of novel and advancing chemical assessment procedures, measures, methods, protocols, methodologies, or models (e.g., high-throughput chemical assessment techniques). EPA will tailor its information gathering efforts as appropriate.

"Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties." (0741-0060)

Response: To date, EPA has gathered extensive use and exposure data for these ten chemicals and believe we have adequate use and exposure info. In fact, some additional information on uses and exposure were submitted during the comment period on the Scope documents and this information was used to refine the problem formulations. We will seek to obtain more if we find we need it.

"Absence of data does not equal no risk, and efforts to obtain data should occur immediately" (0741-0029).

Response: OPPT does not believe that absence of data equals no risk. However, when OPPT does find existing data are not adequate, OPPT will use all available authorities to fill data gaps necessary to conduct fit-for-purpose assessments. As discussed previously, due to the deadlines mandated in TSCA, information must be reasonably available within the constraints of the timeframes imposed.

"When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information" (0741-0059).

Response: EPA will re-evaluate the quality of the key/supporting data/information sources used in previous assessments by applying standards and guidance under amended TSCA.

"EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals, and this does not constitute all "reasonably available" information. By contrast, If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information." (0741-0059)

Response: EPA has not indicated it would rely solely on voluntary requests for information.

"EPA should use section 4, 8(a), 8(c), 11 and 26(a) to fill data gaps, as the information obtained would constitute 'reasonably available information." (0071-0061)

Response: EPA will use available authorities to fill data gaps as appropriate. However, EPA must adhere to the timeframes imposed by TSCA. In the risk evaluation rule, EPA defined reasonably available information to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. And, consistent with the risk evaluation rule preamble, EPA will consider the value of the information that would be obtained through its information collection authorities in judging whether the information is reasonably available.

Alternative Assessment

14. One commenter strongly urged EPA to conduct comprehensive alternative assessments with a priority on hazard assessment for of each of the ten chemicals under consideration. Four of the ten chemicals currently selected by EPA as priority chemicals for risk evaluation have been previously listed by EPA as "acceptable substitutes" under the Significant New Alternatives Policy (SNAP) program that reviews substitutes for ozone-depleting substances within a comparative risk framework. The need now to reevaluate these chemicals will require millions of additional taxpayer dollars for the evaluation itself, as well as potentially millions of dollars in private resources as companies move a second time to replace what EPA deems a hazardous chemical with an acceptable substitute. By using a comprehensive alternatives assessment framework that prioritizes hazard, EPA will be able to reach conclusions about each of the ten chemicals that are far less likely to result in the need for reassessment in a few years (0741-0058).

    Response: In the prioritization rule, EPA stated that an alternative assessment of substitute chemicals is more appropriate during the risk management phase.

Ongoing Section 6(a) rule makings

15. Two commenters included comments regarding the on-going section 6(a) rulemakings that may impact trichloroethylene, methylene chloride, and N-Methylpyrrolidone. One commenter specifically questions EPA's decision not to examine uses addressed by its planned 6(a) rules governing certain uses of TCE, DCM, and NMP, and furthers states that this is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses. "By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is known to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses unless EPA

has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals" (0741-0059).

Another commenter adds that EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals (0741-0060).

Response: Although EPA indicated in the TCE, NMP and MeCl scope documents that EPA did not expect to evaluate the uses assessed in the 2014 or 2015 risk assessment in the TCE, NMP or MeCl risk evaluation, respectively, EPA has decided to evaluate these conditions of use for TCE and NMP in the risk evaluation. EPA is including these conditions of use so that they are part of EPA's determination of whether TCE and NMP presents an unreasonable risk "under the conditions of use," TSCA 6(b)(4)(A). EPA has concluded that the Agency's assessment of the potential risks from these widely used chemicals will be more robust if the potential risks from these conditions of use are evaluated by applying standards and guidance under amended TSCA. In particular, this includes ensuring the evaluations are consistent with the scientific standards in Section 26 of TSCA, the *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act* (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.* EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. It is important to note that conducting these evaluations does not preclude EPA from finalizing the proposed TCE and NMP regulation. On May 10th, 2018 EPA announced it intends to finalize the methylene chloride rulemaking proposed in January 2017. Therefore, EPA will not re-evaluate the paint stripping uses of methylene chloride and will be relying on the previous assessment.

Other

16. One commenters shared information on the "Beyond Science and Decisions" project, a risk methods compendium as a resource for regulators and scientists on key considerations for applying selected dose-response techniques for various problem formulations, with suggested techniques and resources (0741-0057).

    Response: Thank you for this comment and for the suggested resources.

EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA

This response to comment document addresses cross cutting public comments that may be applicable to issues impacting all ten chemicals. The responses here represent EPA's preliminary reactions to some of the comments received, as the Agency has not reached final decisions on the approaches to the 10 risk evaluations. The Agency invites the public to provide additional comments on these Problem Formulation documents if their comments/issues have not been sufficiently addressed.

General comments

1. Many commenters asked for clarification on how the problem formulations will be different than the scope documents. Commenters added that these scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations (0741-0059, 0741-0060). One commenter added that "it is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. The commenter believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified.

   Response: EPA agrees that TSCA requires that scope documents include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. EPA believes the scope documents did that, although without the level of specificity EPA expects for future risk evaluations. As explained in each of the scope documents,

   "To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

   Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for [chemical name]."

   EPA has published the Problem Formulation documents which refine these 10 scope documents. The conceptual models and analysis plans in the problem formulation documents more clearly identify the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations the Administrator expects to consider in risk evaluations for the first ten chemicals. Additional specificity around some of these general components (e.g., particular exposure parameters, points of departure for hazards, susceptible subpopulations based on greater susceptibility) of a risk evaluation cannot be provided until data and models are reviewed and analyses conducted. These activities and further analyses occur during the Analysis Phase of risk evaluation and will be presented in the Draft Risk Evaluation.

Conditions of Use

2. EPA received a number of comments regarding the conditions of use. Commenters urged EPA to consider the chemical substance as a whole and therefore to consider all conditions of use, and that EPA does not have discretion to ignore certain uses (0741-0059, 0735-0052), including de minimis uses (0741-0061). Other commenters added that EPA should consider reasonably foreseeable uses like accidents, misuses, and off-label uses, whole lifecycle of the chemical including legacy, and non-TSCA uses (0741-0061, 0741-0062, 0741-0056, 0741-0029). One commenter specifically questioned the exclusion of accidents, stating that the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks (0741-0059).

   Specifically, regarding legacy uses, two commenters added that legacy uses should be considered (0735-0052) (0741-0057), and others noted that there are six chemicals that contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. These commenters stated that ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations (0741-0060, 0741-0062). Additionally, one commenter added that by-product or contaminant uses should also be added (0741-0057).

   Response: As discussed at length in the preamble to the final risk evaluation rule, based on legislative history, statutory structure and language, and other evidence of Congressional intent, EPA has identified certain activities that may generally not be considered to be conditions of use. EPA does not generally intend to include intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in a chemical substance's risk evaluation. EPA's judgment is supported by the legislative history, and public comment suggesting that "the term 'conditions of use' is not intended to include 'intentional misuse' of chemicals." See, for example Senate Report 114–67, page 7. Similarly, EPA interprets the mandates under section 6(a)–(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), and consequently does not generally intend to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal.

   EPA further explained that it may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. This includes uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks. EPA may determine that there are appropriate regulatory safeguards in place for a particular use or that a particular use is de minimis, and that these uses can be excluded from further assessment as part of the risk evaluation. Finally, EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental

statutes and which EPA does not expect to include in the risk evaluation. See, 82 Fed Reg at 33729-33730 for further details on EPA's reasoning.

EPA also indicated in the preamble to the Risk Evaluation rule, and again in the chemical scope documents, that it intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping. EPA went on to explain that there may be several different technical and policy perspectives in which to consider evaluating the risks of impurities, including to evaluate the potential risks within the scope of the risk evaluations for the impurity itself, within the scope of the risk evaluation for the separate chemical substances that bear the impurity, and not including the impurity within any risk evaluation where EPA has a basis to foresee that the risk from the impurity would be *de minimis* or otherwise insignificant.

The problem formulation document for each of the first 10 chemicals has been refined based on comments and input on the scope documents. The problem formulation more clearly presents what conditions of use and associated exposure pathways will be evaluated in the risk evaluation and provides rationales for EPA's decisions.

Systematic Review

3. Two commenters request that the Agency conduct systematic review to identify the hazard as these methods will strengthen and increase transparency. Specifically, 0741-0052 stated that EPA should conduct hazard identification by following systematic review processes that integrate animal, human, and mechanistic evidence and that EPA should heed the NAS recommendation to conduct risk evaluations by identifying any existing systematic reviews for a chemical substance, determining if the reviews are of high quality, and for those that are, building upon the reviews by incorporating any more recent studies that may have become available since the review was conducted (0741-0052). Another commenter provided a number of ways to improve the Agency's literature search and systematic review strategies to strengthen its evaluations and increase transparency (0741-0057).

   Response: As stated in the Risk Evaluation rule, EPA believes that integrating systematic review into the TSCA risk evaluations is critical to meet the statutory requirements of TSCA. EPA agrees that there are universal components of systematic review that EPA intends to apply in conducting risk evaluations. EPA has also concluded it would be premature to codify specific systematic review methods and criteria since these may change as the Agency gains more experience conducting TSCA risk evaluations.

   Along with the problem formulation documents, EPA is publishing a supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*, which contains details about the systematic review process and the evaluation strategy for assessing data quality that OPPT plans to use for these first ten chemical risk evaluations. Integrating systematic review principles into the TSCA risk evaluation process is critical to develop transparent, reproducible and scientifically credible risk evaluations.

EPA/OPPT plans to implement a structured process of identifying, evaluating and integrating evidence for both the hazard and exposure assessments developed during the TSCA risk evaluation process. The systematic review process will use existing assessments as a starting point to identify relevant references and supplement these with any more recent information. It is expected that new approaches and/or methods will be developed to address specific assessment needs for the relatively large and diverse chemical space under TSCA. Thus, EPA/OPPT expects to document the progress of implementing systematic review in the draft risk evaluations and through revisions of the *Application of Systematic Review in TSCA Risk Evaluations* document, and publication of supplemental documents.

Exposure

4. A number of commenters provided input regarding how the Agency will assess chemical exposures, specifically with regard to engineering controls. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). (0741-0059, 0741-0062, 0741-0029, 0741-0057). Another commenter added that, in evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective. The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls (0741-0060).

   Response: OPPT's approach for developing exposure assessments for workers is to use best available information to construct realistic exposure scenarios based on data and information regarding real-world use of chemicals. When appropriate, in the risk evaluation, OPPT will use exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-by-case basis for a given chemical.

5. There were a number of comments urging EPA to assess aggregate exposures within populations in the problem formulations, and stating that failing to do so would underestimate the risk of the chemicals. (0735-0052, 0741-0057, 0741-0060, 0741-0061, 0741-0029)

   Response: The statute requires that the Agency describe whether aggregate (or sentinel) exposures were considered, see 15 USC 2605(b)(4)(F)(ii); whichever exposure assessment method is ultimately used will be accompanied by an explanation in the Risk Evaluation. In conducting an aggregate exposure assessment, EPA may also include exposures from non-TSCA uses, e.g., as part of background; whether and how to account for such exposures will be

evaluated on a case-by-case basis. EPA will consider whether to assess aggregate exposure when developing the exposure assessment during the Analysis Phase of the Risk Evaluation.

6. Two commenters asked how EPA will incorporate cumulative risk, as well as aggregate, in the first 10 risk evaluations. Commenters added, to properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. (0741-0060, 0741-0061)

   Response: Cumulative exposure is not required under the statute. EPA retains the discretion to conduct a cumulative assessment but has not yet determined whether to do so for any of the first 10 risk evaluations. However, EPA may ultimately determine that for a certain chemical or category a cumulative exposure assessment is appropriate for certain endpoints.

Hazard

7. One commenter asked EPA not to prejudge the absence of adverse effects for particular end-points at the scoping stage but to defer such conclusions until the systematic review phase of its risk evaluation as the law requires (0741-0060).

   One commenter expressed concern that EPA says in all the chemical scoping documents in the Section on Environmental Hazards that it expects to consider other studies, including data from alternative test methods such as computational toxicology, bioinformatics, high-throughput screening methods, read-across data, etc. Many of these alternative test methods, and particularly their application to risk assessment, are still emerging and, although promising, have serious limitations. However, if utilized prematurely or incorrectly, these tools could allow for the rapid and erroneous exoneration of harmful chemicals. These tools lack complete biological coverage, cannot presently evaluate the potential toxicity associated with chemical metabolism and absorption, and have the potential for high false negatives relative to whole animal studies (0741-0062).

   Response: EPA does not intend to prejudge any conclusions before completing the systematic review process supporting the risk evaluations. OPPT is aware of the status of alternative test methods with regard to the methodological validation, standardization and acceptance (e.g., established OCSPP or OEC Test Guideline vs. basic research approach). Regardless of the level of regulatory or international recognition, data from other studies and alternative test methods can inform risk evaluation if they are determined to be consistent with the best available science and can inform the weight of the scientific evidence. Like other, more traditional testing studies, studies conducted using non-guideline approaches or using alternative test methods will be evaluated for quality and relevance following the process described in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*. In addition, all risk evaluations will be subject to public comment and independent peer review. OPPT anticipates use of data from alternative test methods.

   TSCA section 26(h) requires that, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, EPA must use scientific information, technical procedures, measures, methods, protocols, methodologies, or models consistent with the best available

science. TSCA section 26(i) requires EPA to make decisions under TSCA sections 4, 5, and 6 based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).

8. One commenter stated that three chemicals (carbon tetrachloride, methylene chloride and 1-bromopropane) have data showing a high ozone depletion potential and that this should fall within the scope of the risk evaluation (0742-0060).

   Response:

   Regulation of ozone-depleting substances (ODS) falls under the jurisdiction of the Clean Air Act, administered by EPA's Office of Air and Radiation. Because ozone depletion risks are adequately assessed and effectively managed under the Clean Air Act, EPA does not expect to include ozone-depletion potential in risk evaluations for carbon tetrachloride, methylene chloride or 1-bromopropane. EPA regulations under Sections 601-607 of the Clean Air Act phase out the production and import of class I and class II ODS ([HYPERLINK "https://www.epa.gov/ods-phaseout"]) with limited exceptions. Carbon tetrachloride is subject to these regulations, addressing its ozone-depletion risks. Furthermore, under Section 612 of the CAA, EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ODS. New chemicals that are proposed as substitutes are reviewed in coordination with OCSPP's New Chemicals Program, and significant new uses of existing chemicals are also reviewed under the SNAP program. Various environmental and health risks of methylene chloride and 1-bromopropane (n-propyl bromide), including their ozone-depletion potential, have been evaluated for specific uses under the SNAP program.

Health Protective Defaults

9. A number of commenters urged EPA to use health-protective defaults if the agency lacks information specific to a chemical, and health-protective methods to quantify risk when characterizing risk (0741-0052, 0741-0057, 0741-0062). Specifically, for cancer, a commenter highlighted the NAS recommendation that EPA include a factor to account for human variability in response to carcinogens, as EPA's current approach inaccurately assumes that there is no variability in response. Similarly, EPA should increase or add factors that address cancer and non-cancer susceptibility during early life stages (0741-0057).

   One commenter urged EPA not to use MOE (margin of exposure) as an analysis method in the risk evaluation process, as MOE is not an estimate of risk—it is a single number that is a version of the "bright line" approach like the Reference Dose (or Reference Concentration for inhalation doses) (0741-0057).

   Response: EPA does not want to *a priori* preclude the use of any methods or data types, to allow its evaluations to change as science advances. EPA will utilize current policies, models, and screening methods, but is committed to being consistent with the best available science and weight of the scientific evidence approaches to guide the Agency in using this information. EPA recognizes the advancing science to inform risk evaluation and will not discourage the use of new methods as long as they are consistent with the standards in section 26 of TSCA. EPA also recognizes that different approaches require different types and amounts of data and will select

and employ methods that are fit for purpose within the context of a particular risk evaluation. In some cases, it may be necessary to utilize default parameters in modeling and risk calculations, and to utilize conservative assumptions, whereas in other cases assumptions may be replaced with specific or specialized data. It should also be noted, in addition, their use will be peer reviewed, and the public will have the opportunity to comment on them during the public comment periods.

EPA has utilized the MOE approach in previous risk assessments, citing its utility. However, EPA does agree with comments that there are numerous ways to characterize risk, of which MOE is just one. There will be risk scenarios where one approach may be better than another and, as commenters correctly pointed out, the science of risk characterization is still evolving, particularly for non-cancer hazards. Hence, OPPT will use risk characterization approach(es) suitable for the purpose of the risk evaluation and that the best available science and data support. EPA does not agree with the commenter that the use of MOEs is never appropriate.

Confidential business information (CBI)

10. A number of commenters added comments regarding CBI. Two requested EPA require that claims of confidential business information be fully substantiated by industry and not used to conceal critical information from the public (0741-0052, 0741-0057, 0074-0059). Another added that EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired (0741-0060).

    One commenter added that the strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available EPA must review it (0741-0059).

    Additionally, this commenter raised the question as to whether this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. Historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act (0741-0059).

    Response: TSCA requires that CBI claims must be asserted and substantiated concurrently with the submission of information, except for information that is deemed exempt under TSCA section 14(c)(2).

    The risk evaluation rule does clarify that the agency does consider CBI as "reasonably available information" and will utilize it in risk evaluations were relevant.

The *Strategy for Conducting Literature Searches for each TSCA Scope document* described the procedure for searching the public literature which does not include searching "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information". However, OPPT is searching internal information it may possess as part of the process of conducting the risk evaluations. This is discussed in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.*

EPA will comply with TSCA section 14 review and disclosure requirements for data/information that is claimed confidential and deemed relevant for the risk evaluation.

Potentially exposed and susceptible subpopulations

11. Commenters provided feedback regarding EPA's approach to identifying "potentially exposed or susceptible subpopulations." One commenter suggested that EPA address susceptible sub-populations, following recommendations from the National Academies of Sciences (NAS) to identify susceptible sub-populations based on established extrinsic and intrinsic factors that increase vulnerability (0741-0057).

    Another commenter suggested the language provided in the scopes was general "boilerplate" descriptions of such subpopulations, adding that further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor that TSCA requires (0741-0060). Similarly, a commenter asked for more clarification in the problem formulation documents of those populations with greater susceptibility (0741-0059).

    Another commenter encouraged EPA to consider for every chemical review: (1) occupational exposures that are often at much higher exposure levels than the general public, both acutely and chronically, and can be concurrent with other chemical exposures at the workplace; (2) fence-line communities who also face multiple exposures to multiple chemicals and suffer from many chronic health conditions and health inequalities; (3) sensitive time periods during life, such as pregnancy and during childhood; (4) tribal communities where cultural and lifestyle considerations may result in very different exposure profiles and where there are often disproportionate adverse health outcomes; and (5) general variability in human responses. The commenter encouraged EPA to actively seek input from fence-line and other impacted communities, occupational workers at manufacturing, processing, distributing, or recycling facilities, concerned members from the public, and tribal communities and incorporate their concerns in the Agency's evaluations where appropriate." (0741-0029)

    A commenter added comments specifically regarding occupational exposure: Occupational workers exposed during the manufacture, processing, disposal, etc. of these chemicals should always be considered separately as a susceptible population. Furthermore, the consideration of exposed workers should always include the potential for pregnant women and consider both women and men of childbearing age as a vulnerable population when assessing the risk (0741-0029 and 0741-0059).

Finally, one commenter urged the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. The commenter also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment (0741-0061).

Response: While EPA wholly agrees that protecting potentially exposed or susceptible subpopulations is an important part of EPA's mandate, the process for identifying the subpopulations considered in each risk evaluation will be case specific and, consistent with the directive in section 6(b)(4)(A), tailored as relevant to the risk evaluation. Furthermore, EPA will use the best available science and prevailing guidance, such as recommendations of the NAS, in defining and assessing such subpopulations.

Every risk evaluation must consider any 'potentially exposed or susceptible subpopulations' determined to be relevant to the risk evaluation under the conditions of use. However, potentially exposed or susceptible populations and subpopulations can vary depending on the chemical and conditions of use being evaluated. EPA is required by statute to consider relevant potentially exposed or susceptible subpopulations, which could include children, pregnant women, and other subpopulations as appropriate for the assessment. For example, when appropriate, EPA will include specific life-stages exposure scenarios which may be more representative of various exposures that affect children.

Likewise, if workers are determined to be a population likely to be exposed to a chemical during its conditions of use, this population would be included as a 'potentially exposed or susceptible subpopulation' and therefore considered in the risk evaluation. In fact, in the scope documents, EPA identified both workers and consumers as susceptible subpopulations on the basis that they are more exposed than the general population to chemicals and/or products that the general population does not work with or use. EPA acknowledged in the scope documents that measurement and evaluation methods for these, and potentially other, subpopulations is still being refined.

EPA welcomes information from communities and will use it to further refine risk evaluations.

To this end, EPA has already sought input from specific populations and public health experts in implementing TSCA and will continue to do so. For example, EPA has had discussions on several occasions with the National Tribal Toxics Council to receive input on tribal lifeways and exposures. OPPT and the NTTC continue to collaborate on ways to consider tribes in conducting potentially exposed or susceptible subpopulations analyses for Draft Risk Evaluations. OPPT has also had several meetings with AFL-CIO about workers as potentially exposed or susceptible subpopulations and ways in which worker exposure information could be identified and provided for use in the risk evaluation process. OPPT has also sought advice and input regarding children as a susceptible subpopulation from the Children's Health Protection Advisory Committee (CHPAC) through a meeting and recommendations addressing the formal request from EPA for guidance on how risk evaluation should address children. CHPAC's recommendations can be found [HYPERLINK "https://www.epa.gov/sites/production/files/2017-04/documents/2017.03.30_chpac_tsca_letter.pdf"].

IRIS Assessments

12. A few commenters urged EPA to use existing IRIS assessments (0741-0061, 0741-0062). Specifically, EPA should rely on existing IRIS assessments for hazard identification, and moving forward, EPA should complete hazard identification or add additional studies only through a systematic review process, which integrates animal, human and mechanistic evidence as recommended by the recent NAS report (0741-0057). EPA does not need to revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address (0074-0060).

    Response: As discussed in the scope documents, where applicable, OPPT has used IRIS documents as a starting point for identifying key and supporting toxicity studies and initial hazard identification. However, EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. Specifically, EPA will screen information developed after the completion of any IRIS assessment and evaluate the relevant information using OPPT's structured process described in the documents *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act* (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.*

Information Gathering

13. EPA received a number of comments on information gathering.

    "EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA [sections] 4 and 8 to obtain additional information. The scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is reasonably available information. Additionally, any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps." (0741-0059).

    Response: The commenter is correct, as the scope documents should refer to "reasonably available information", not "readily available". In the risk evaluation rule, EPA defined reasonably available information to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. Below EPA has collated a non-exhaustive list of the information activities associated with collecting reasonably available information. EPA notes that it selected the first 10 chemicals for risk evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development.

Generate: EPA explained in the risk evaluation rulemaking that reasonably available information includes information that could be generated through testing, where that information can be generated and synthesized within the statutory timeframes and would be of sufficient value to merit the testing. As of now, EPA has not identified the need for any such testing for the first 10 chemicals. In the timeframe allotted to initiate the risk evaluation process and develop the scoping documents for the initial ten chemicals subject to risk evaluation following the 2016 amendments to TSCA, EPA consulted a variety of information sources, both internally and externally, and currently believes the information obtained through these investigations is sufficient to make the necessary determinations. As we have previously indicated (for instance, in the scope documents for the first ten chemicals), in the future prioritization (and pre-prioritization) processes, EPA will have additional time prior to risk evaluation to evaluate data landscapes and judge whether testing would be appropriate. While the timeframes for these first 10 risk evaluations have necessarily constrained EPA's ability to require testing, EPA does not currently see the need for testing to complete these risk evaluations.

Obtain: EPA conducted extensive and varied data gathering activities for each of the first 10 chemicals, including:

(1) Conducted extensive and transparent searches of public databases and sources of scientific literature, government and/or industry sector or other reports, etc. [See supplemental file, Strategy for Conducting Literature Searches, associated with each of the ten chemicals on the chemical's webpage].
(2) Searched EPA TSCA 8(e) and CBI submission holdings for data on the first ten chemicals.
(3) Consulted a variety of sources to identify conditions of use of the initial ten chemicals. These sources included information reported to EPA (including Chemical Data Reporting and the Toxics Release Inventory), literature searches, proprietary reports, trade publications, and reports developed for prior EPA and international assessments. To identify formulated products containing <chemical>, EPA searched for safety data sheets (SDS, formerly referred to as material safety data sheets (MSDS)) using internet searches, EPA Chemical and Product Categories (CPCat) data, the National Institute for Health's (NIH) Household Product Database, and other resources in which SDS could be found. Each SDS was then cross-checked with company websites to make sure that each product SDS was current. EPA also communicated with companies, industry groups, international regulatory agencies, and non-governmental organizations, to make sure the list of uses was correct, complete, and up-to-date. A preliminary list of uses was presented to the public for comment ahead of a public meeting as part of a use document for <chemical>. Those public comments as well as information from other engagements with stakeholders were integrated into this scoping document.
(4) Conducted a market analysis of conditions of use using proprietary databases and repositories.
(5) Conducted many outreach meetings with chemical manufacturers, processors, chemical users, non-governmental organizations, trade organizations, and other experts, including other State and Federal Agencies (e.g., Dept of Defense, NASA, OSHA, NIOSH, FDA and CPSC) for each of the initial ten chemicals [See Docket(s)

[HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca" \l "ten"]] to support development of conditions of use documents [see Dockets
[HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca" \l "ten"]] and scope documents

(6) Published conditions of use documents, solicited public comment/input on conditions of use of the initial ten chemicals, convened a public meeting and opened dockets to receive written public comments. See the following link for additional information: [HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca"]
(7) Solicited public input on Scope documents and encouraged submission of additional data/information regarding the scope for each of the initial ten chemicals
(8) Consulted existing systematic review approaches and methods to inform development of data evaluation step of systematic review under TSCA
(9) Worked with chemical manufacturers, industry associations, other federal agencies, state governments, unions, non-governmental organizations, and international regulatory partners to discuss additional data/information that would inform risk evaluations and scenarios where people could be exposed to the initial ten chemicals. As a result, EPA received additional study reports regarding hazard information, (e.g. PV29), occupational monitoring data from DoD, data from OSHA on worker exposures, and a variety of information from a wide swath or stakeholders on how chemicals are used in specific industries.
(10) Published Problem Formulation documents and solicited public input to obtain further information useful for developing the draft risk evaluation

Synthesize: EPA has synthesized reasonably available information in several phases during the risk evaluation process for the first chemicals, as follows:

(1) Developed conditions of use documents that synthesize the data/information obtained from searches and meetings with stakeholders for each the initial ten chemicals.
(2) Conducted title and abstract screening on all references obtained from the literature searches, synthesizing this information into 'on topic' and 'off topic' bins for all ten chemicals [see supplemental file, Bibliography, for each of the ten chemicals on the chemical's webpage].
(3) Developed Scope documents that synthesize conditions of use and lifecycle information for each chemical to describe the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in the risk evaluation and link them to the plan for the analyses to be included in the risk evaluation.
(4) Synthesized existing methods/approaches to systematic review to develop the evaluation strategies to assess data/information quality as described in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*
(5) Synthesized additional input/data/information received on scope documents in developing problem formulation documents that synthesize conditions of use and lifecycle information for each chemical to describe the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in the risk evaluation and link them to the plan for the analyses to be included in the risk evaluation.

(6) Consulted within EPA, across major media programs, to integrate and synthesize (cross-walk) the nexus between TSCA and other major media statutes and regulatory programs (e.g., CAA, CWA, SDWA, RCRA).

EPA agrees that it makes sense to view information that can be obtained through testing as "reasonably available" in some instances – especially information that can be obtained through short-term testing, where it can be obtained within the relevant statutory deadlines and the information would be of sufficient value to merit the testing. EPA will consider use of its information gathering authorities under section 8 on a similar basis – i.e., considering the statutory deadlines and the value the additional information would likely have in reducing uncertainty in its fit-for-purpose evaluations. As discussed in the prioritization rulemaking, EPA will seek to generally ensure that sufficient information to complete a risk evaluation exists and is available to the Agency prior to initiating the evaluation. For these first ten risk evaluations, EPA believes that these are generally data-rich chemicals, and the use of our data gathering authority is not warranted at this time. However, EPA also recognizes that there may be circumstances where additional information may need to be developed within the time frames of the risk evaluation process. This may include information developed through the use of novel and advancing chemical assessment procedures, measures, methods, protocols, methodologies, or models (e.g., high-throughput chemical assessment techniques). EPA will tailor its information gathering efforts as appropriate.

"Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties." (0741-0060)

Response: To date, EPA has gathered extensive use and exposure data for these ten chemicals and believe we have adequate use and exposure info. In fact, some additional information on uses and exposure were submitted during the comment period on the Scope documents and this information was used to refine the problem formulations. We will seek to obtain more if we find we need it.

"Absence of data does not equal no risk, and efforts to obtain data should occur immediately" (0741-0029).

Response: OPPT does not believe that absence of data equals no risk. However, when OPPT does find existing data are not adequate, OPPT will use all available authorities to fill data gaps necessary to conduct fit-for-purpose assessments. As discussed previously, due to the deadlines mandated in TSCA, information must be reasonably available within the constraints of the timeframes imposed.

"When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information" (0741-0059).

Response: EPA will re-evaluate the quality of the key/supporting data/information sources used in previous assessments by applying standards and guidance under amended TSCA.

"EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals, and this does not constitute all "reasonably available" information. By contrast, If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information." (0741-0059)

Response: EPA has not indicated it would rely solely on voluntary requests for information.

"EPA should use section 4, 8(a), 8(c), 11 and 26(a) to fill data gaps, as the information obtained would constitute 'reasonably available information." (0071-0061)

Response: EPA will use available authorities to fill data gaps as appropriate. However, EPA must adhere to the timeframes imposed by TSCA. In the risk evaluation rule, EPA defined reasonably available information to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. And, consistent with the risk evaluation rule preamble, EPA will consider the value of the information that would be obtained through its information collection authorities in judging whether the information is reasonably available.

Alternative Assessment

14. One commenter strongly urged EPA to conduct comprehensive alternative assessments with a priority on hazard assessment for of each of the ten chemicals under consideration. Four of the ten chemicals currently selected by EPA as priority chemicals for risk evaluation have been previously listed by EPA as "acceptable substitutes" under the Significant New Alternatives Policy (SNAP) program that reviews substitutes for ozone-depleting substances within a comparative risk framework. The need now to reevaluate these chemicals will require millions of additional taxpayer dollars for the evaluation itself, as well as potentially millions of dollars in private resources as companies move a second time to replace what EPA deems a hazardous chemical with an acceptable substitute. By using a comprehensive alternatives assessment framework that prioritizes hazard, EPA will be able to reach conclusions about each of the ten chemicals that are far less likely to result in the need for reassessment in a few years (0741-0058).

    Response: In the prioritization rule, EPA stated that an alternative assessment of substitute chemicals is more appropriate during the risk management phase.

Ongoing Section 6(a) rule makings

15. Two commenters included comments regarding the on-going section 6(a) rulemakings that may impact trichloroethylene, methylene chloride, and N-Methylpyrrolidone. One commenter specifically questions EPA's decision not to examine uses addressed by its planned 6(a) rules governing certain uses of TCE, DCM, and NMP, and furthers states that this is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses. "By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is known to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses unless EPA

has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals" (0741-0059).

Another commenter adds that EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals (0741-0060).

Response: Although EPA indicated in the TCE, NMP and MeCl scope documents that EPA did not expect to evaluate the uses assessed in the 2014 or 2015 risk assessment in the TCE, NMP or MeCl risk evaluation, respectively, EPA has decided to evaluate these conditions of use for TCE and NMP in the risk evaluation. EPA is including these conditions of use so that they are part of EPA's determination of whether TCE and NMP presents an unreasonable risk "under the conditions of use," TSCA 6(b)(4)(A). EPA has concluded that the Agency's assessment of the potential risks from these widely used chemicals will be more robust if the potential risks from these conditions of use are evaluated by applying standards and guidance under amended TSCA. In particular, this includes ensuring the evaluations are consistent with the scientific standards in Section 26 of TSCA, the *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act* (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.* EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. It is important to note that conducting these evaluations does not preclude EPA from finalizing the proposed TCE and NMP regulation. On May 10th, 2018 EPA announced it intends to finalize the methylene chloride rulemaking proposed in January 2017. Therefore, EPA will not re-evaluate the paint stripping uses of methylene chloride and will be relying on the previous assessment.

Other

16. One commenters shared information on the "Beyond Science and Decisions" project, a risk methods compendium as a resource for regulators and scientists on key considerations for applying selected dose-response techniques for various problem formulations, with suggested techniques and resources (0741-0057).

    Response: Thank you for this comment and for the suggested resources.